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Function Description

1 General

The Evita 4/Evita 2 dura is a time-cycled, constant-volume long-term ventilator for adults and children with a minimum body weight of 3 kg.

The Evita 4/Evita 2 dura can be used for the following ventilation modes:

IPPV	Intermittent Positive Pressure Ventilation, controlled and assisted constant-volume ventilation with the following options: • CPPV = (Continuous Positive Pressure Ventilation) Controlled ventilation at a continuous positive airway pressure. • PLV = (Pressure Limited Ventilation) Pressure-limited, constant-volume ventilation. • AutoFlow® = for automatic optimizing of the inspiratory flow. • IRV = (Inversed Ratio Ventilation) Ventilation at a reversed I:E ratio.
SIMV	Synchronized Intermittent Mandatory Ventilation, weaning method for spontaneously breathing patients with the following options: • PLV = (Pressure Limited Ventilation) Pressure-limited, constant-volume ventilation. • AutoFlow® = for automatic optimizing of the inspiratory flow.
MMV	Mandatory Minute Volume Ventilation, spontaneous breathing with automatic synchronizing of mandatory ventilation and required minute volume of the patient. With the following options: • PLV = (Pressure Limited Ventilation) Pressure-limited, constant-volume ventilation. • AutoFlow® = for automatic optimizing of the inspiratory flow.
SB	Spontaneous Breathing, spontaneous breathing at atmospheric pressure conditions.

CPAP	Continuous Positive Airway Pressure, spontaneous breathing at a positive airway pressure.
ASB	Assisted Spontaneous Breathing, pressure-assisted spontaneous breathing.
BIPAP	Biphasic Intermittent Positive Airway Pressure, pressure-controlled ventilation combined with free spontaneous breathing during the entire respiratory cycle and adjustable pressure assistance on CPAP level.
APRV	Airway Pressure Release Ventilation, spontaneous breathing on two pressure levels with extended time ranges, independently variable.

Special methods:

Apnoea-Ventilation	For automatic change-over to volume-cycled mandatory ventilation in the event of apnoea. In this case the Evita 4 gives an alarm upon expiry of the set alarm time ($T_{\text{apnoea}} >$) and activates constant-volume ventilation.
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ILV (optional)	Independent Lung Ventilation, bilateral, differentiated, synchronized ventilation with two Evita 4 units.
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Diagnosis:

Intrinsic PEEP measurement	For determination of the intrinsic PEEP in air trapping.
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Occlusion pressure measurement	For assessment of the respiratory drive during spontaneous breathing.
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Monitoring:

- Airway pressure (P_{aw})
- Expiratory minute volume (MV)
- Inspiratory O_2 concentration (FiO_2)
- Inspiratory breathing gas temperature (T)
- Expiratory CO_2 concentration ($etCO_2$)
- Inspiratory tidal volume (V_{TI})
- Apnoea time
- Tachypnoea monitoring to detect dead-space-intensive spontaneous breathing.

2 Basic Principle

2.1 Evita 4

The Evita 4 consists of three components which communicate via a CAN (fast serial interface).

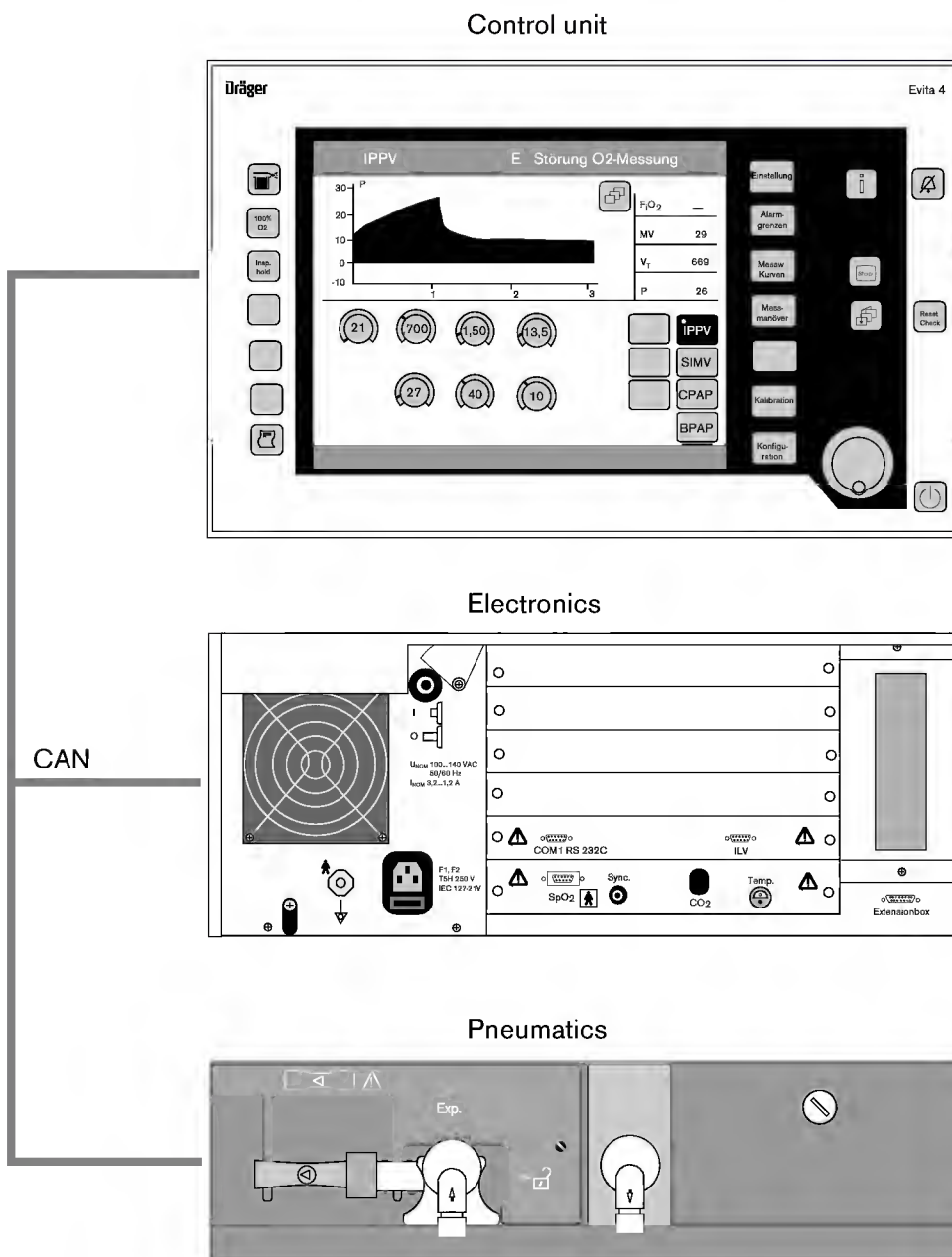


Fig. 1: Basic components

2.1.1 Control Unit

The control unit is the interface between the machine and the operator. The control unit serves to make adjustments, to display measured values and to activate alarms. In the control unit the display, membrane keypad, touch screen and Graphics Controller PCB are accommodated.

2.1.2 Electronics

The electronics is the central control unit of the Evita 4. It includes the CPU 68332 PCB, the CO₂-Carrier PCB with the Processor Board PCB and Power Supply PCB and the power supply unit (Communication PCB, Paediatric Flow PCB and the optional SpO₂ PCB).

2.1.3 Pneumatics

The pneumatics controls the pneumatic valves following preset ventilation parameters. It includes an independent microprocessor system and the valve control. In the pneumatics the Pneumatics Controller PCB, the HPSV Controller AIR/O₂ PCB, the PEEP valve, the mixer, the pressure connection, the flow sensor and the O₂ sensor are accommodated.

2.2 Evita 2 dura

The Evita 2 dura has three components which communicate via a CAN (fast serial interface).

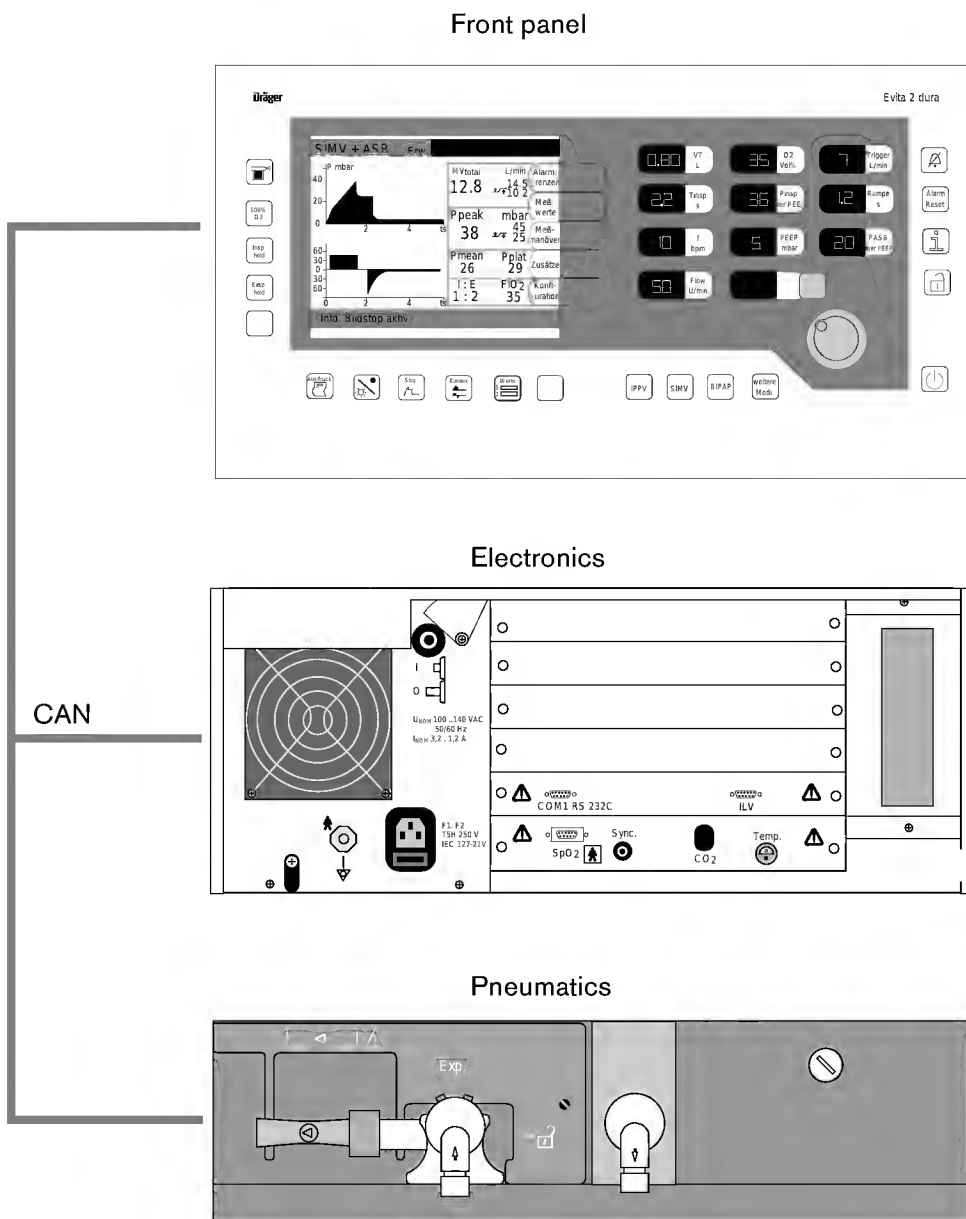


Fig. 2: Basic components

2.2.1 Front Panel

The front panel is the interface to the user. The front panel allows the user to adjust the desired values. It displays the measured values and alarms. The front panel also contains the LCD, the membrane keyboard, the 7-segment displays, the Frontpanel PCB, and the 7-Segment PCB.

2.2.2 Electronics

The electronics is the central control unit of the Evita 2 dura. It contains the CPU 68332 PCB, the power supply unit, the CO₂-Carrier PCB including the Processor Board PCB (optional), and the Power Supply PCB (optional). The Communication PCB, the Paediatric Flow PCB, and the SpO₂ PCB are optional features.

2.2.3 Pneumatics

The pneumatics controls the pneumatic valves according to pre-set ventilation parameters. It has an independent microprocessor system and the control elements for the valves. The Pneumatic Controller PCB, the HPSV Controller AIR/O₂ PCB, the PEEP valve, the mixer, the pressure connection, the flow sensor and the O₂ sensor are part of the pneumatics.

2.3 Basic principle Evita 4

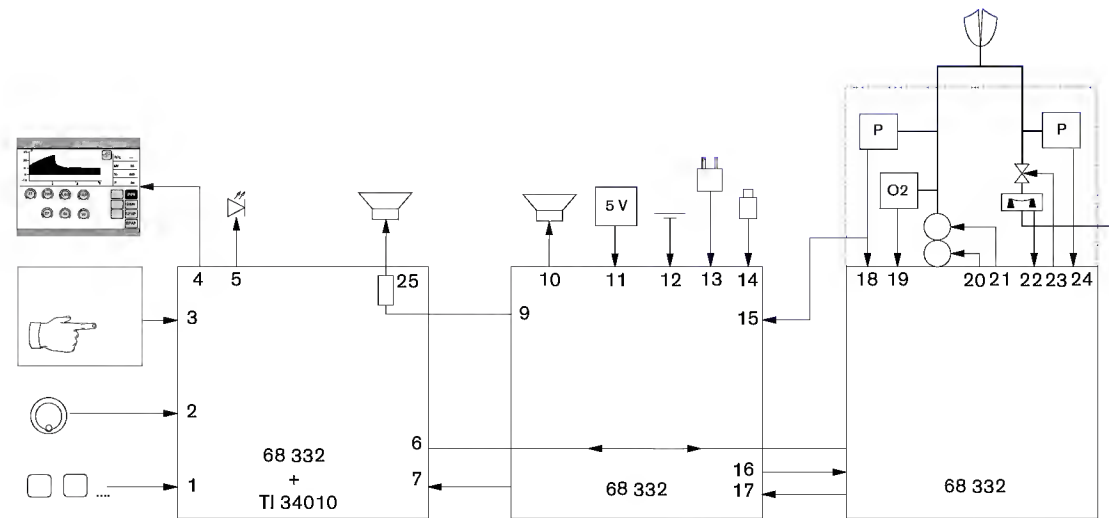


Fig. 3: Basic principle

- | | | | |
|----|--|----|--|
| 1 | Keys | 13 | Supply voltages |
| 2 | Rotary knob including acknowledgement (by pressing knob) | 14 | Mains switch |
| 3 | Touchscreen | 15 | Second inspiratory P_{aw} |
| 4 | TFT display 640 x 480 | 16 | Reset pneumatics processor and venting |
| 5 | Information LEDs and Alarm LEDs | 17 | Electronics processor reset and second loudspeaker alarm |
| 6 | CAN bus | 18 | Inspiratory P_{aw} |
| 7 | Graphics processor reset | 19 | O ₂ sensor |
| 8 | not applicabel | 20 | FiO ₂ (HPSV mixer) |
| 9 | Loudspeaker with sound chip | 21 | AIR (HPSV mixer) |
| 10 | Second loudspeaker (piezo) | 22 | Flow sensor |
| 11 | Voltage monitoring (activates reset of the processors and the piezo) | 23 | Expiratory valve with PEEP |
| 12 | Rechargeable battery (Goldcap capacitor) | 24 | Expiratory P_{aw} |
| | | 25 | Loudspeaker with current monitoring |

2.4 Basic principle Evita 2 dura

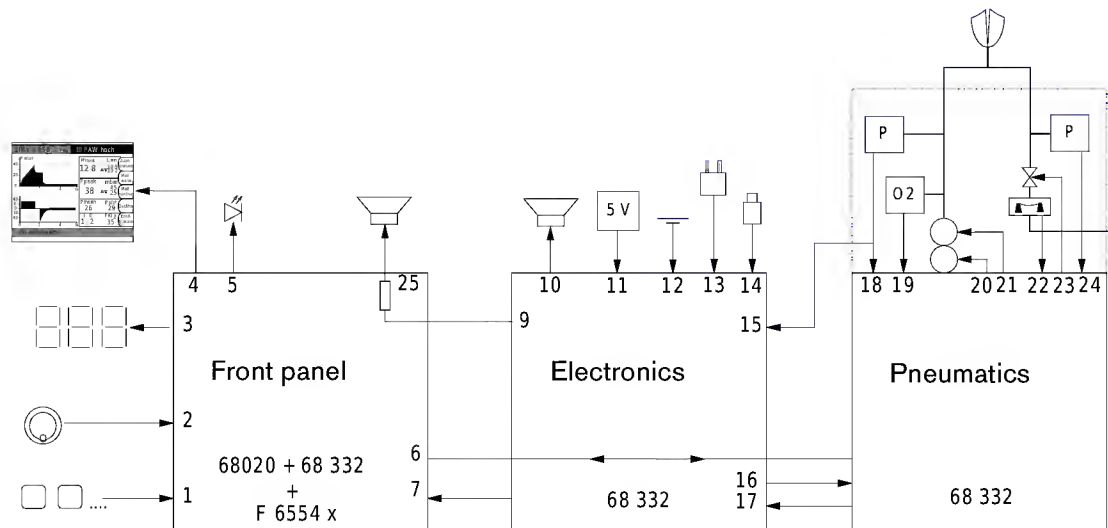


Fig. 4: Basic principle

- | | |
|--|---|
| 1 Keys | 13 Supply voltages |
| 2 Control knob with acknowledgment function (press) | 14 Power switch |
| 3 7-segment displays | 15 Second Paw, inspiratory |
| 4 LCD or TFT display, 640 x 480 | 16 Pneumatics processor reset and venting |
| 5 Indicator LEDs and alarm LEDs | 17 Electronics processor reset and second loudspeaker alarm |
| 6 CAN bus | 18 Paw, inspiratory |
| 7 Reset graphics processor | 19 O ₂ sensor |
| 8 Not applicable | 20 FiO ₂ (HPSV mixer) |
| 9 Loudspeaker with soundchip | 21 Flow (HPSV mixer) |
| 10 Second loudspeaker (piezo) | 22 Flow sensor |
| 11 Voltage monitoring (activates processors reset and the piezo) | 23 Expiratory valve with PEEP |
| 12 Battery (Goldcap capacitor) | 24 Paw, expiratory |
| | 25 Loudspeaker with current monitoring |

3 CPU 68332 PCB

The CPU 68332 PCB is integrated in the electronic unit of the Evita 4. The board includes an independent processor system, two external interfaces, three internal interfaces, the loudspeaker control and a serial EEPROM.

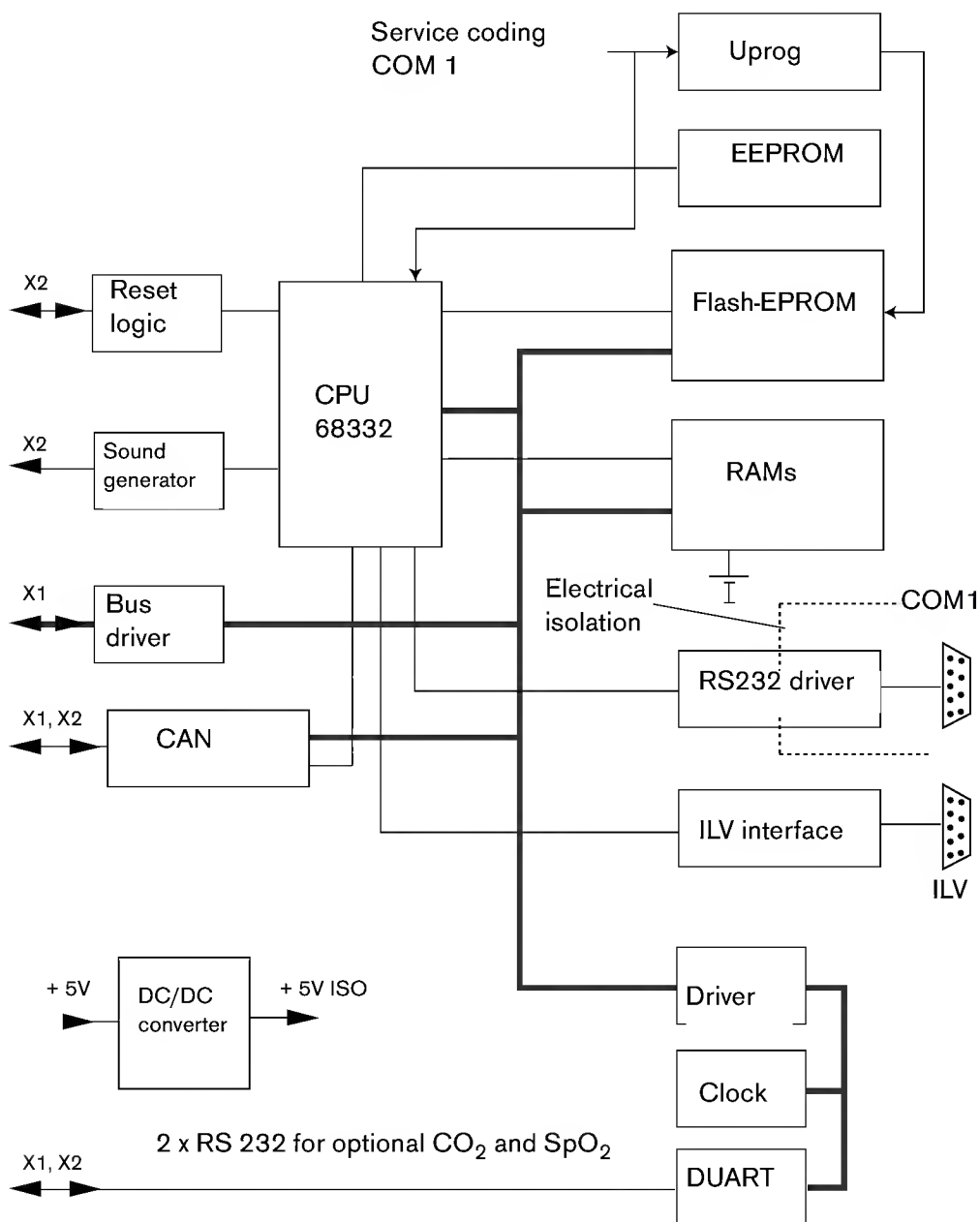


Fig. 5: Block diagram CPU 68332 PCB

3.1 EEPROM

The EEPROM is connected to the synchronized, serial interface 68332. The EEPROM characterizes the Evita 4 (enabled options, serial number, etc.). When replacing the CPU 68332 PCB the EEPROM has to be transferred to the new printed circuit board.

3.2 Processor System

The processor system comprises a 68332 CPU, a 512 kByte RAM and a 1 MByte flash EPROM (electrically programmable and erasable read-only memory). The RAM has a battery back-up. When the battery is being replaced a Goldcap capacitor ensures voltage supply of the RAMs. Programming of the flash EPROMS is only possible if the system identifies the "SERVICE-Q" signal.

3.3 RS232 Interface

The CPU 68332 PCB provides an RS232 interface in the Evita 4. This interface, referred to as COM1, is electrically isolated from the Evita 4 by means of optocouplers.

3.4 ILV Interface

The ILV interface is required for bilateral ventilation with two Evita 4 units. The ILV interface is not electrically isolated. Pin 3 of the ILV interface is provided with a filler plug to prevent confusion with the RS232 interface.

3.5 Driver

The driver adjusts the access times between the 68332, the clock and the DUART.

3.6 Clock

The clock gives the current time. It has a battery back-up and continues to operate even after the Evita 4 has been switched off.

3.7 DUART

The DUART (Dual Universal Asynchronous Receiver/Transmitter) has two serial interfaces and digital inputs and outputs. The serial interfaces are intended for connection of the SpO₂ and CO₂ modules.

3.8 DC/DC Converter

The DC/DC converter provides the voltage supply (+5 V ISO) required for the interface. The input voltage of the DC/DC converter is +5 V.

3.9 CAN

The CAN interface is a fast, serial interface (Controller Area Network). The control unit, electronics and the pneumatics communicate via a CAN interface at a transmission rate of 800 kBit/s.

3.10 Bus Driver

The address bus, the data bus and the check-back signals are transferred by the bus driver to the motherboard. The 68332 CPU communicates with the optional printed circuit boards located on the motherboard via the bus driver. Currently, it is only the Pediatric Flow PCB (Neoflow option).

3.11 Sound Generator

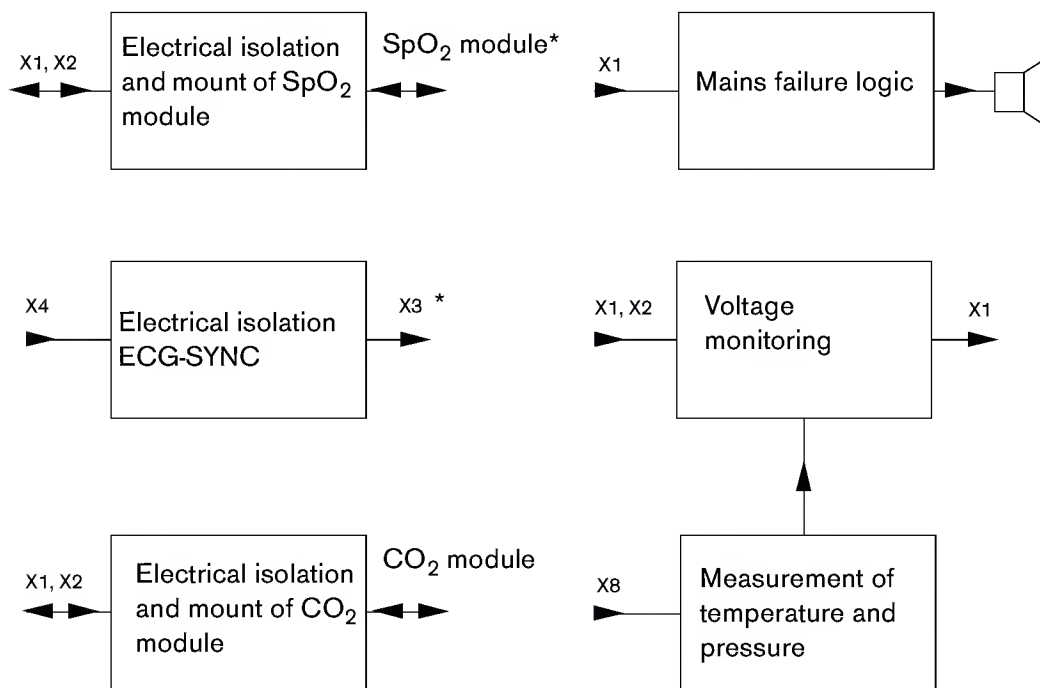
The sound generator controls the loudspeaker in the control unit. The sound generator incorporates the volume control and sound generation for the loudspeaker. The volume is controlled by the DUART.

3.12 Reset Logic

The CPU 68332 can reset the control unit and the pneumatics. A reset can also be activated if the voltage falls below or exceeds +5 V. The pneumatics can also be reset by the CPU 68332 PCB. The reset logic controls and displays the resets.

4 CO₂ Carrier PCB

The CO₂ Carrier PCB is located in the electronic unit of the Evita 4. The printed circuit board includes the mount and electrical isolation of the CO₂ module and the SpO₂ module, the mains failure logic, the temperature measurement and the voltage monitoring.



* Optional

Fig. 6: CO₂ Carrier PCB block diagram

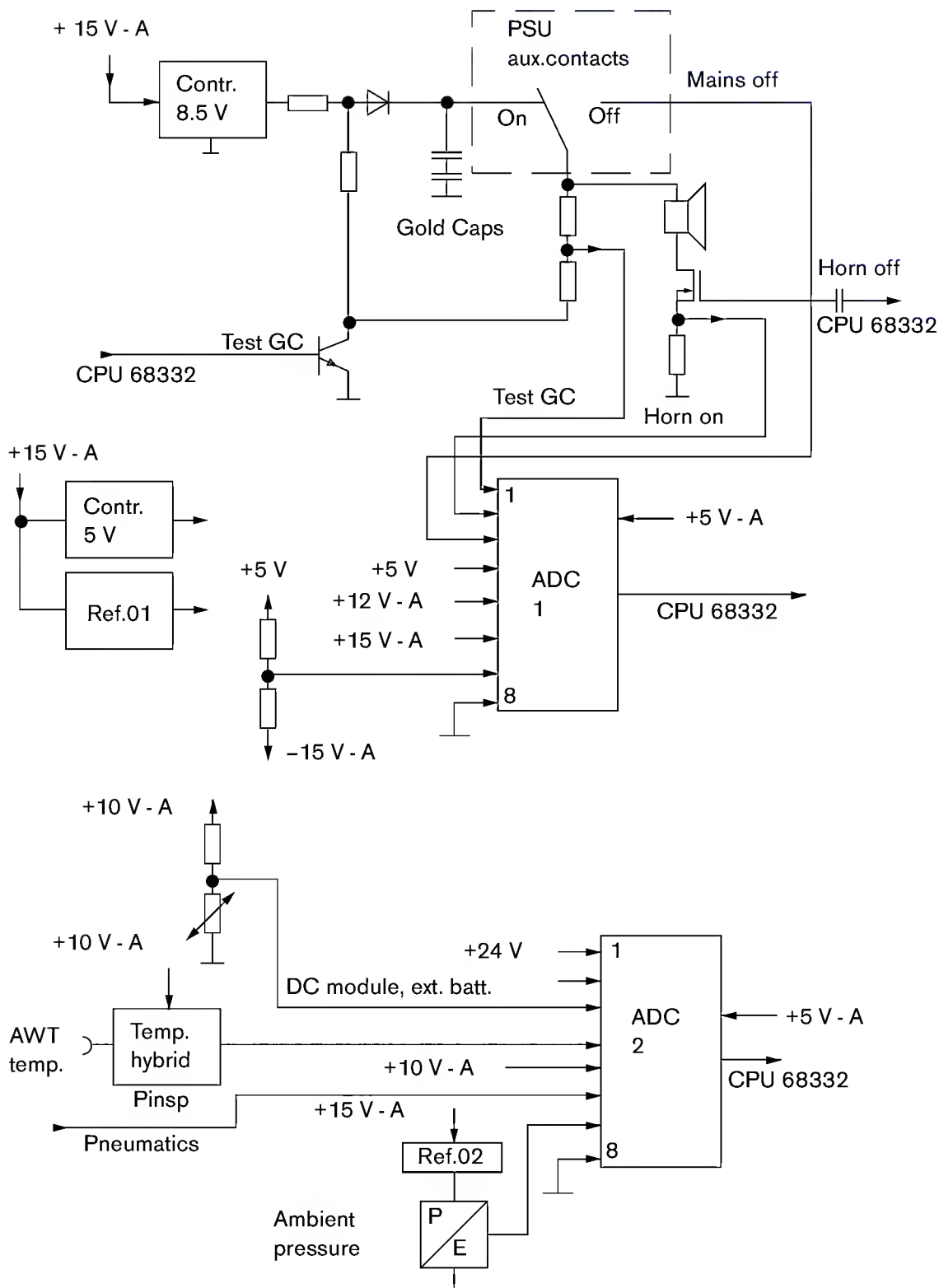


Fig. 7: CO₂ Carrier PCB (part 1) block diagram

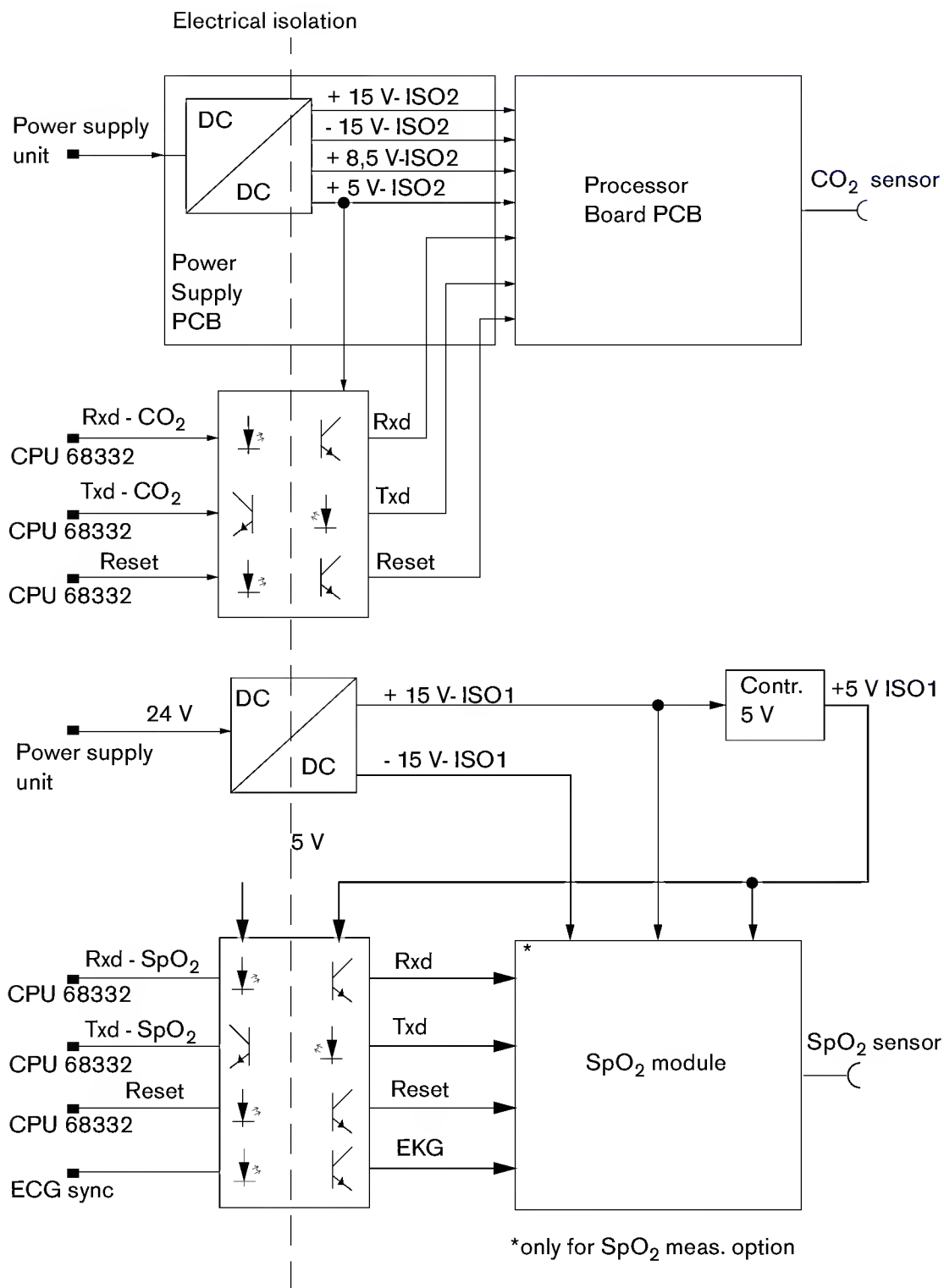


Fig. 8: CO₂ Carrier PCB (part 2) block diagram

4.1 Electrical Isolation

Electrical isolation is made by means of optocouplers. The printed circuit board is coupled with the SpO₂ and CO₂ modules by plug-in contacts. The X3 connector is part of the optional SpO₂ module and is not fitted.

4.2 Power Failure Logic

The power failure logic monitors the power supply. In the event that a power failure occurs while the Evita 4 is operating an audible alarm will sound.

4.3 Voltage Monitoring

Monitoring is provided for the voltages ± 15 V, +10 V, +24 V, +12 V and +5 V. The relevant voltages are transmitted to a voltage divider and read out by an A/D converter which in turn is read out by the CPU 68332 PCB.

4.4 Measurement of Temperature and Pressure

The temperature is measured by an NTC thermistor detector. The signals are processed in a temperature hybrid. The output signal of the temperature hybrid is transmitted to an A/D converter which is read out by the CPU 68332 PCB.

A pressure sensor measures the ambient pressure and transmits the values to the A/D converter.

5 CO₂ Measurement

The CO₂ measuring system comprises three modules:

- Sensor
- Processor Board PCB
- Power Supply PCB.

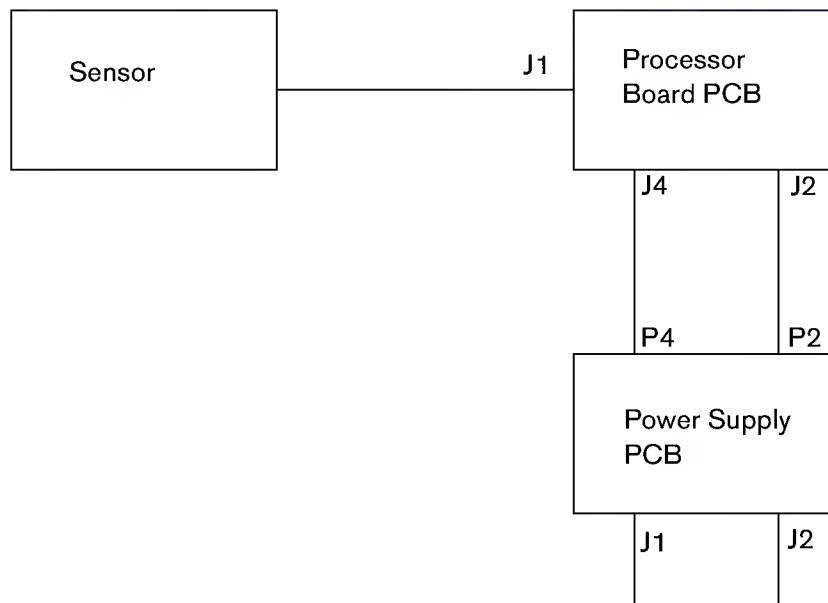


Fig. 9: CO₂ measurement block diagram

5.1 CO₂ Sensor

A CO₂ metering unit and a microprocessor system are integrated in the CO₂ sensor. A lamp generates a light spectrum up to 4.5 µm. This light spectrum is transmitted via the cuvette and two sapphire lenses to detectors. The detectors emit electrical signals depending on the CO₂ concentration. These signals are analyzed by the microprocessor and transmitted to the Processor Board PCB via a RS232 interface. Build-up of condensation is prevented by keeping the temperature of the CO₂ metering unit at a constant level.

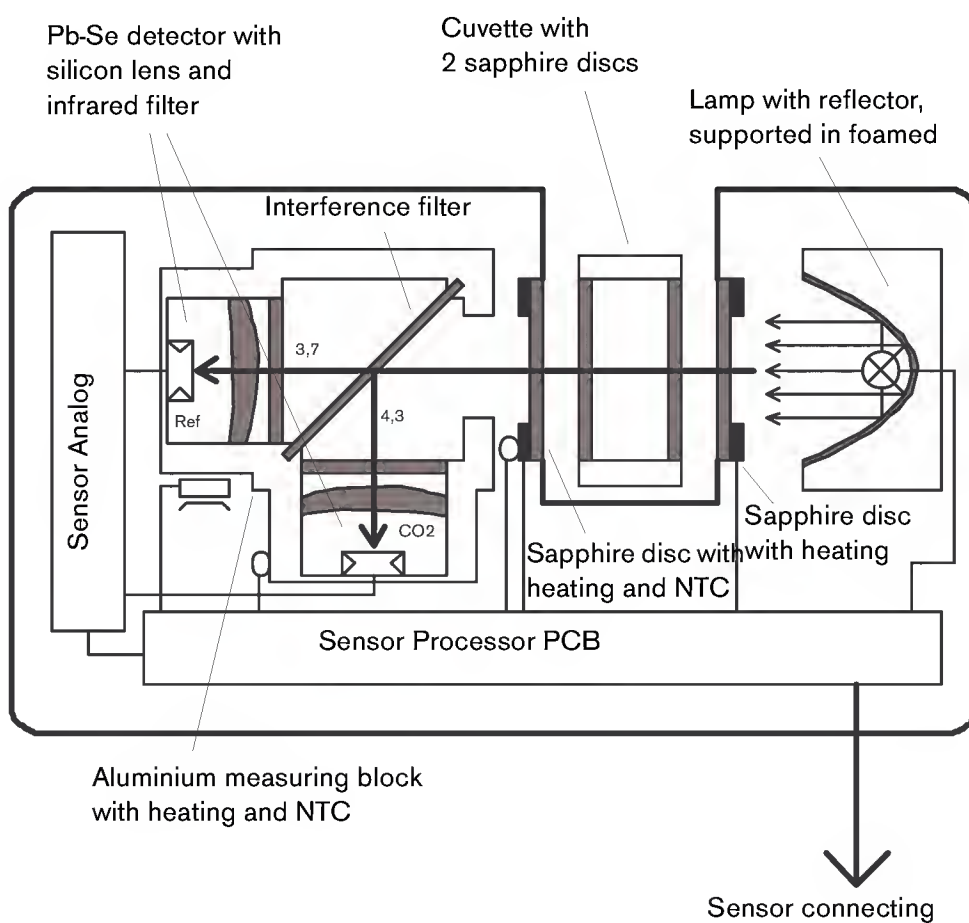


Fig. 10: Sectional view of CO₂ sensor

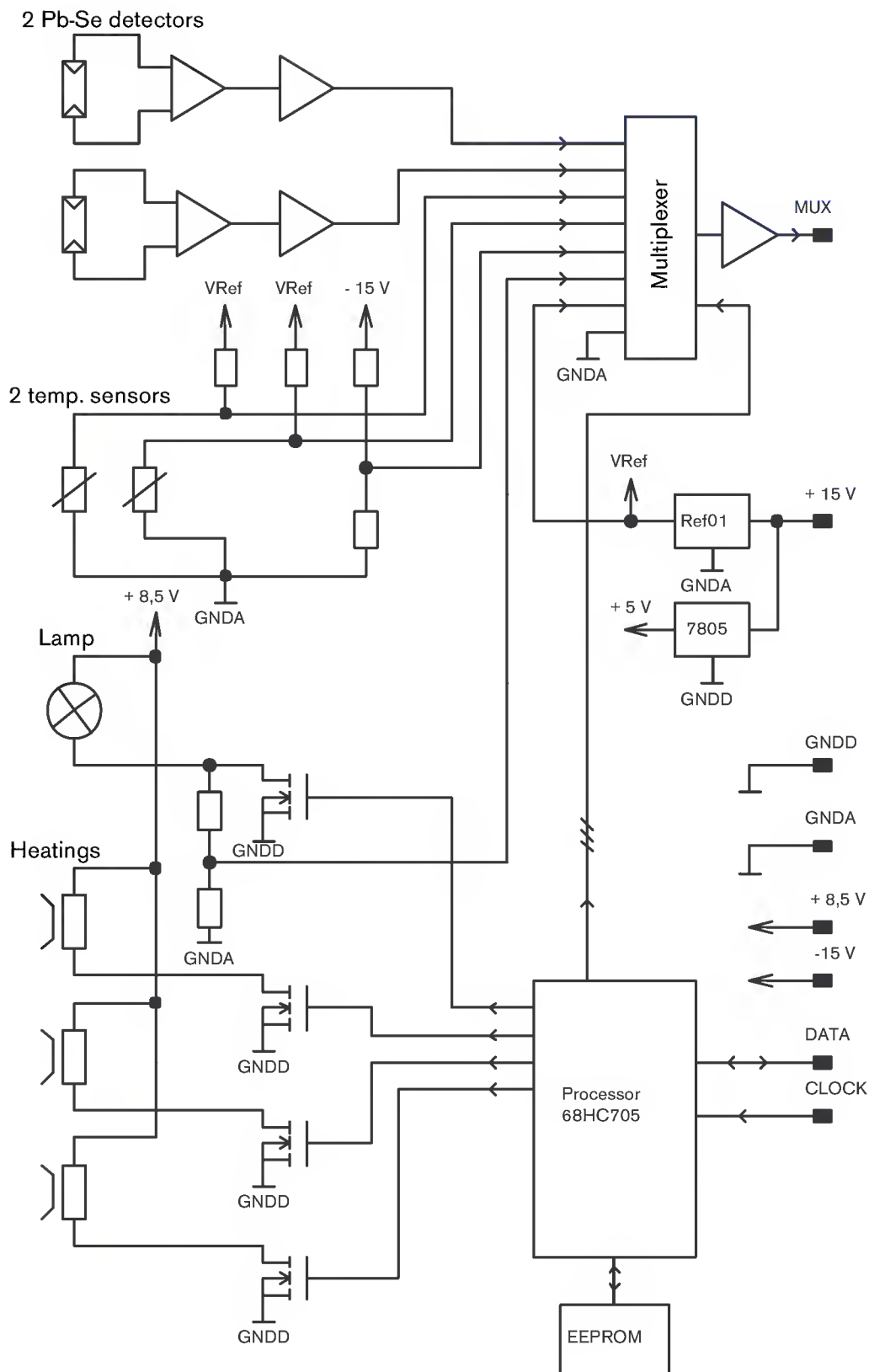


Fig. 11: CO₂ sensor block diagram

5.2 Processor Board PCB

The Processor Board PCB controls the heating of the CO₂ metering unit and the measured-data transfer of the CO₂ sensor.

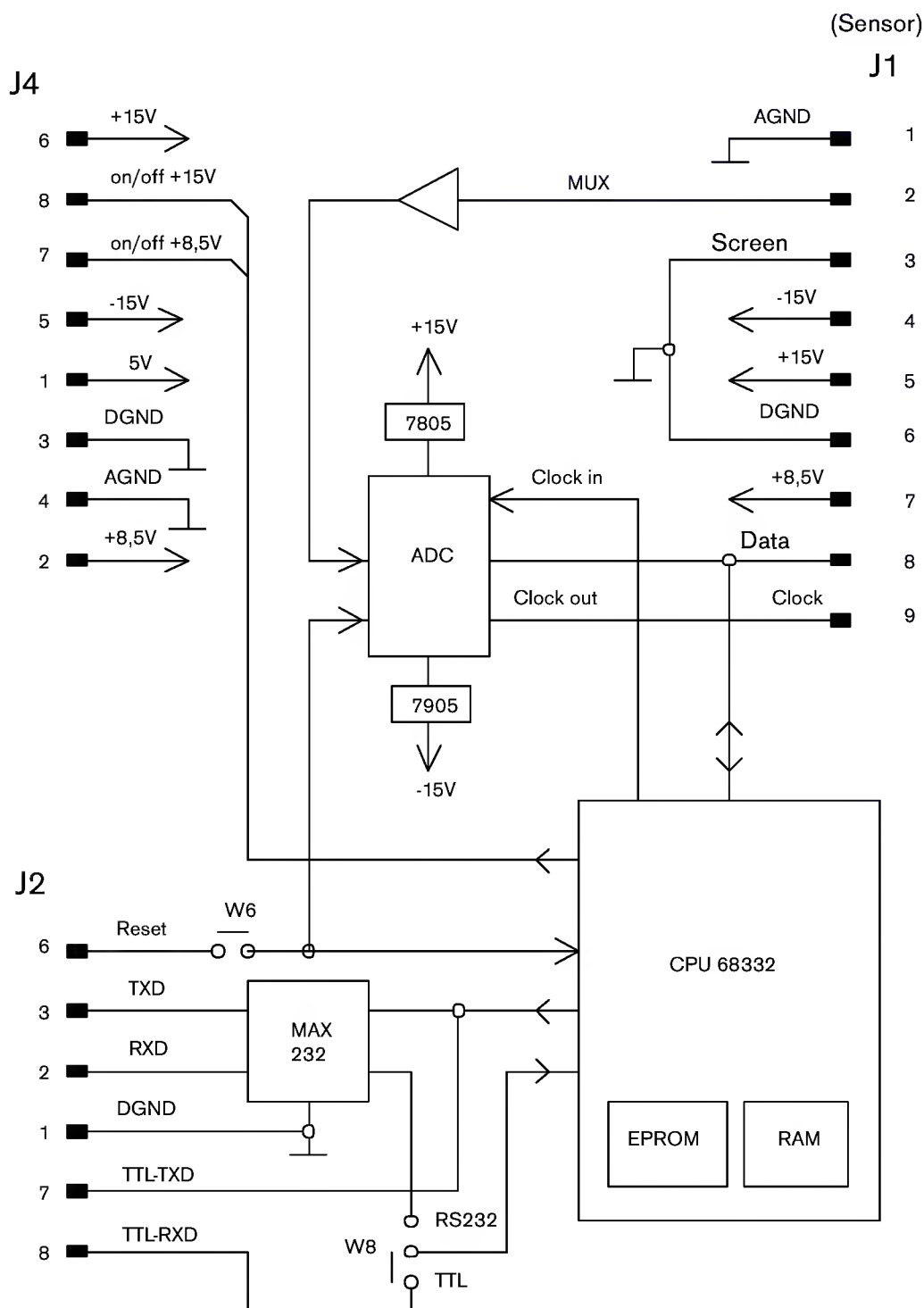


Fig. 12: Processor Board PCB

5.3 Power Supply PCB

The Power Supply PCB provides the supply voltages for the Processor Board PCB and the CO₂ sensor. The supply voltages are electrically isolated from the Evita 4. The measured CO₂ values are transferred to the CPU 68332 PCB via the Power Supply PCB.

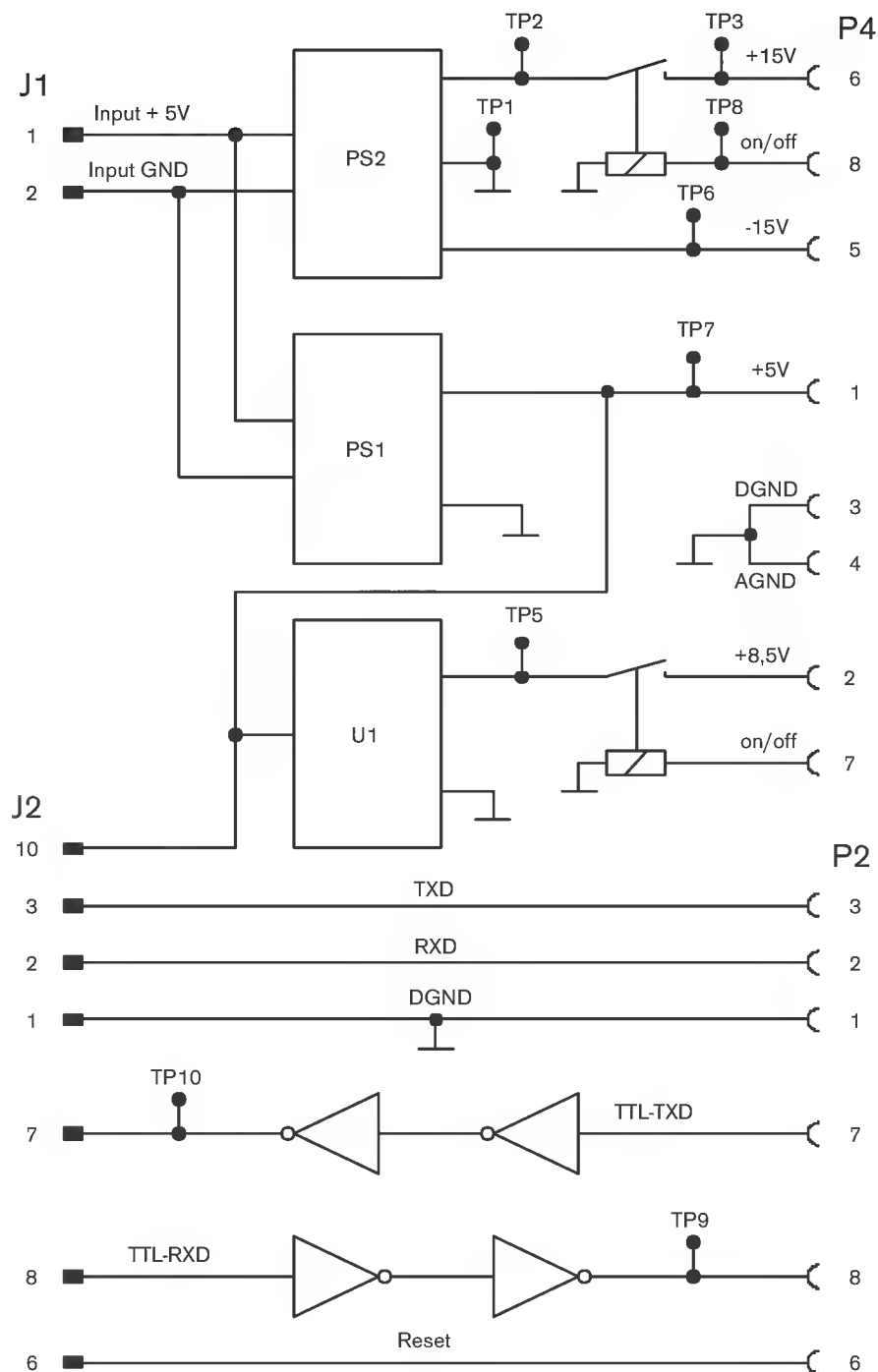


Fig. 13: Power Board block diagram

6 Power Supply Unit

The power supply unit provides the following output voltages:

- +24 V
- +15 V
- -15 V
- +12 V
- +5 V

The Evita 4 power supply unit is a switched-mode power supply unit. The output voltages are short-circuit-proof. A DC module is optionally available ensuring voltage supply in case of power failure or short duration transport of the Evita 4.

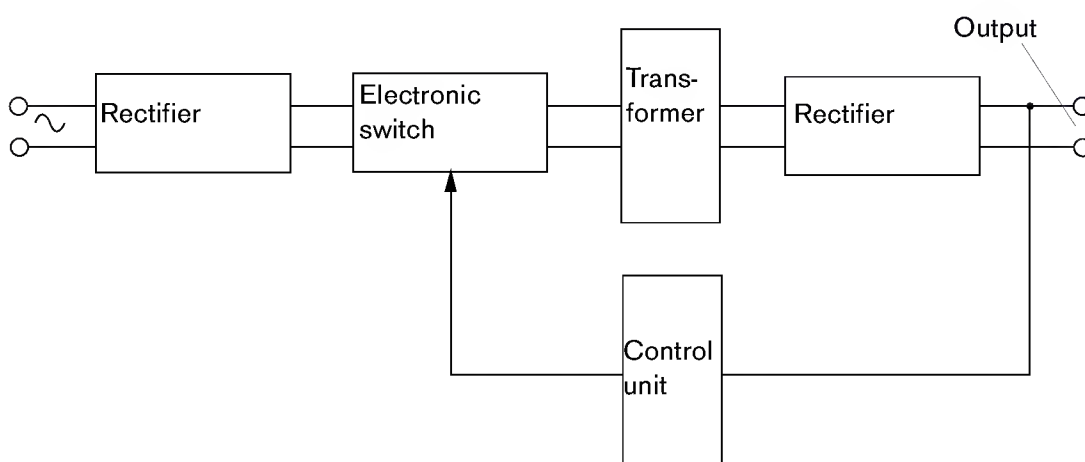


Fig. 14: Functional diagram of a switched-mode power supply unit

7 Graphics Controller PCB

The Graphics Controller PCB is located in the Evita 4 control unit. The printed circuit board includes an independent processor system, the voltage supply of the control unit, the interface to the electronics and the display control.

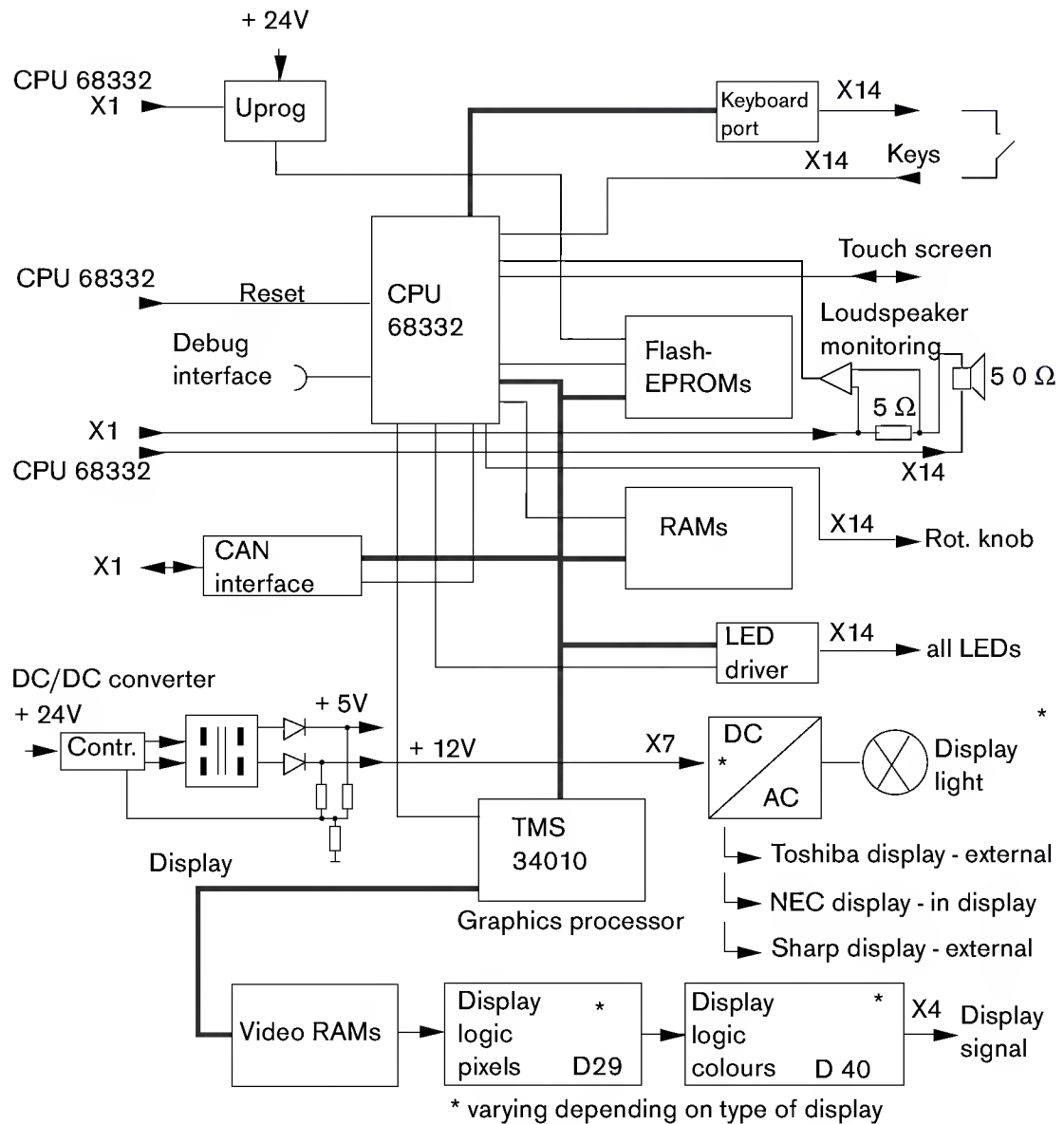


Fig. 15: Graphics Controller PCB block diagram

7.1 Processor System

The processor system comprises a 68332 CPU, a 256 kByte RAM and a 2 MByte flash EPROM (electrically programmable and erasable read-only memory).

7.2 Uprog

Uprog generates the voltage required for programming the flash EPROMs. An enable logic prevents unintentional supply of the programming voltage to the flash EPROMs.

7.3 Reset

The Graphics Controller PCB operates independently and is fitted with its own reset generator. The display can be reset by the CPU 68332 PCB.

7.4 Loudspeaker Monitoring

The loudspeaker monitoring checks the loudspeaker function. The current passing through the loudspeaker is measured by a resistor and then analyzed.

7.5 Keyboard Port and LED Driver

The keyboard and the LEDs are arranged in a 3x8 matrix array. The LEDs are controlled by transistors which also select the keyboard columns. A driver module controls the selection of lines of the LEDs in the matrix. The 68332 CPU scans the keyboard using Schmitt trigger.

7.6 Display Control

The video processor TMS 34010 controls the image processing, generates the synchronized signals for the display and displays the image to be represented by means of the display logic. The video RAM is the video processor memory having a capacity of 512 kByte. The video RAM stores the video processor program, the video processor data and the displayed image.

7.7 CAN Interface

The CAN interface is a fast serial interface (Controller Area Network). The control unit, the electronics and the pneumatics communicate via a CAN interface. The transmission rate is 1 Mbit/s.

7.8 DC/DC Converter

The DC/DC converter supplies +5 V and +12 V for the voltage supply of the control unit. The input voltage of the DC/DC converter is +24 V. Since the +5 and +12 V voltages are generated directly on the Graphics Controller PCB there is a tolerance of $\pm 2.5\%$. The maximum power consumption of the control unit is 1.5 A for +5 and 2.2 A for +12 V.

8 Communication PCB (Optional)

The Communication PCB is located in the electronic unit of the Evita 4. The printed circuit board includes an independent processor system, the voltage supply of the interfaces, an internal CAN interface, an external CAN interface, two RS232 interfaces and two analog outputs.

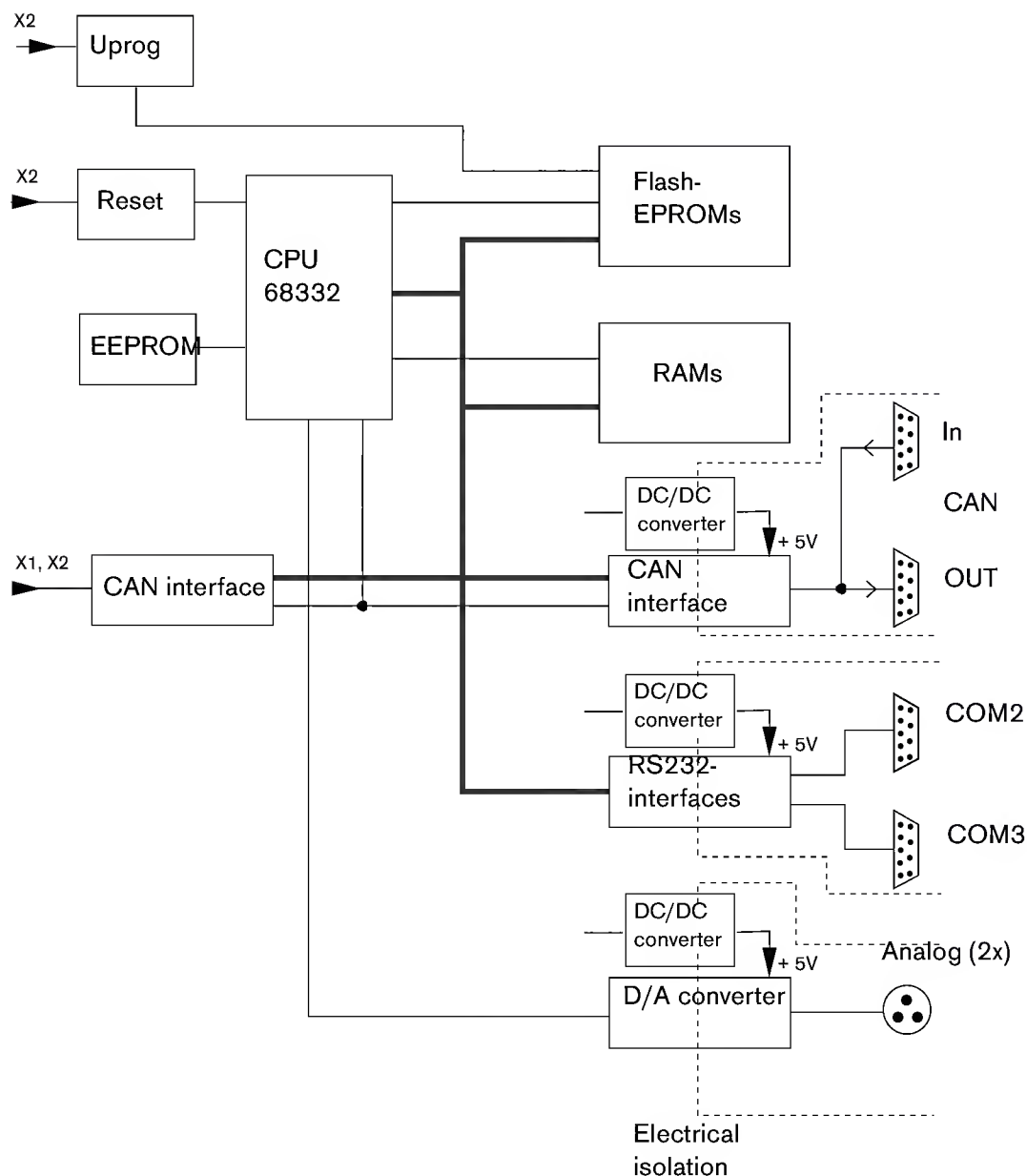


Fig. 16: Communication PCB block diagram

8.1 Processor System

The processor system comprises a 68332 CPU, a 512 kByte RAM and a 1 MByte flash EPROM (electrically programmable and erasable read-only memory).

8.2 Uprog

Uprog generates the programming voltage for the flash EPROMs. An enable logic ensures that the programming voltage is not accidentally supplied to the flash EPROMs.

8.3 Reset

The reset logic generates a defined reset after power-up. The CPU 68332 can be reset by the CPU 68332 PCB.

8.4 CAN Interfaces

The Communication PCB is not connected to the data bus of the CPU 68332 PCB. The data are transmitted via an internal CAN interface (Controller Area Network – fast, serial interface). The external CAN interface is electrically isolated from the Evita 4 by optocouplers.

8.5 RS232 Interfaces

The Communication PCB is provided with two RS232 interfaces additionally available in the Evita 4. These interfaces are referred to as COM2 and COM3 and are electrically isolated from the Evita 4 by optocouplers.

8.6 Analog Outputs

The analog outputs supply voltages between 0 V and 4.095 V. The assignment of analog outputs is freely selectable. The resolution of the output voltage is 1 mV per bit.

8.7 DC/DC Converter

The DC/DC converters supply +5 V ISO each for the voltage supply of the interfaces. The input voltages of the DC/DC converters are +5 V.

8.8 EEPROM

The EEPROM stores internal data of the interface and has a capacity of 2 kByte.

9 Paediatric Flow PCB (Optional)

The Paediatric Flow PCB is located in the electronic unit of the Evita 4. The printed circuit board includes 2 flow measuring channels to connect the Babylog flow sensor, 1 four-channel multiplexer, 1 twelve-bit A/D converter, 1 interface to the CPU 68332 PCB.

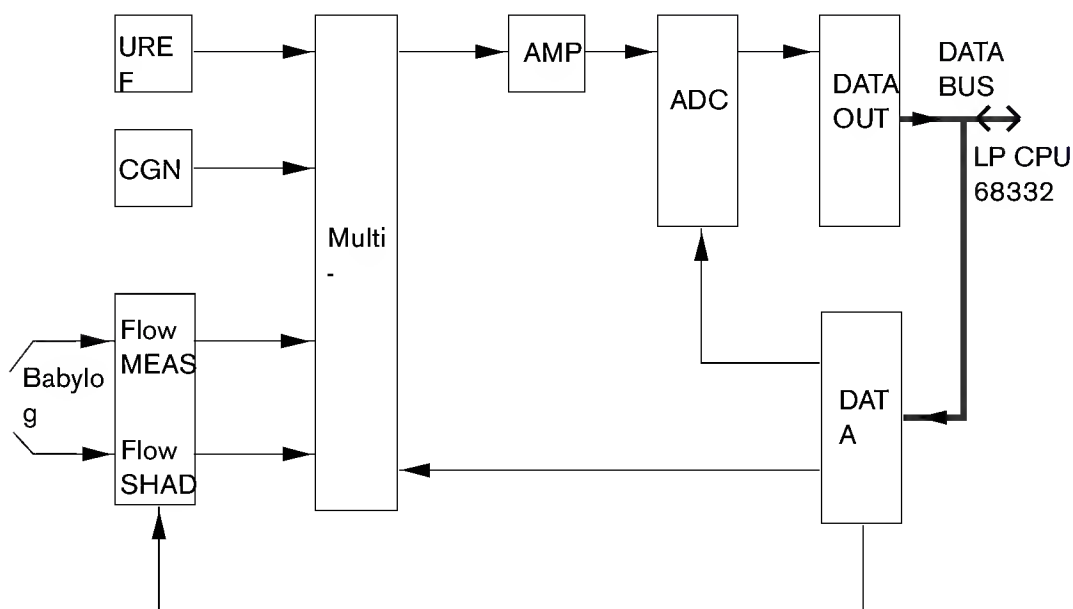


Fig. 17: Paediatric Flow PCB block diagram

9.1 Flow Measurement

The flow is measured with the Babylog flow sensor which has two measuring wires. One measuring wire is covered by a plastic bar. The Babylog flow sensor recognizes the direction of the flow which is analyzed by a measuring bridge.

9.2 Multiplexer

The multiplexer consists of four analog-value selectors. The analog-value selectors are controlled by the software. The multiplexer transmits the flow sensor measurement signals, CGND and UREF LIMIT via a buffer (AMP) to an A/D converter (ADC).

9.3 A/D Converter

The input voltage of the A/D converter ranges from 0 V to 10 V. The A/D converter converts the flow measurement values into digital data. The CPU PCB controls the A/D converter and the multiplexer via an interface (DATA OUT; DATA IN). The voltage drop across the multiplexer, the buffer and the A/D converter is measured using the UREF LIMIT reference voltage and can be taken into account when measuring the flow.

10 Pneumatics Controller PCB

The Pneumatics Controller PCB is located in the pneumatics of the Evita 4. The printed circuit board comprises the following features:

- Supply pressure measurement
- Inspiratory and expiratory airway pressure measurement
- Oesophageal pressure measurement
- Flow measurement
- Measurement of the O₂ concentration in the breathing gas
- Fan monitoring
- Solenoid valve control
- PEEP valve control
- Interface to the HPSV Controller PCBs
- CAN interface
- 68332 CPU with RAM and flash EPROM
- Serial EEPROM for storage of device configuration.

10.1 Pneumatics Controller PCB block diagram

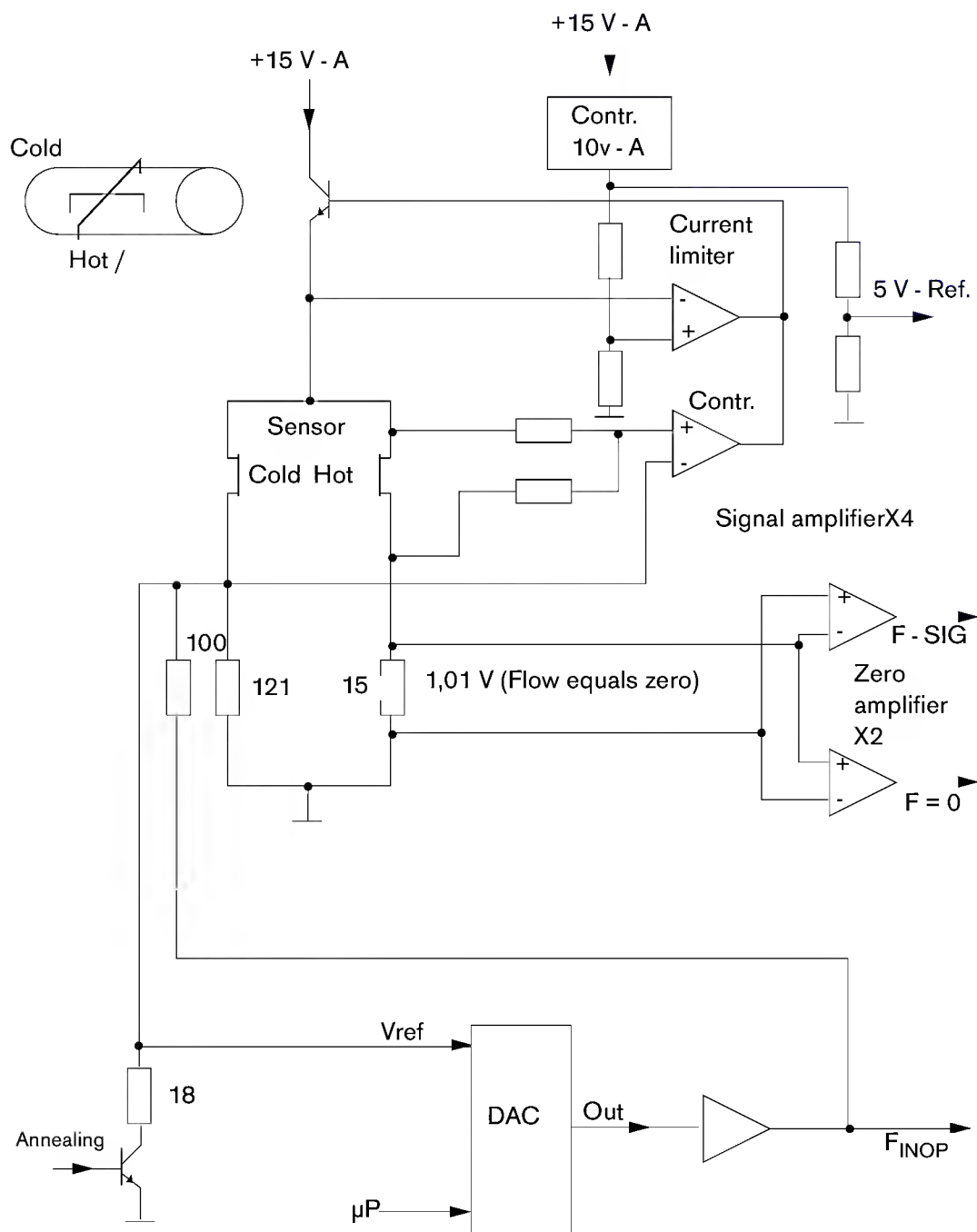


Fig. 18: Pneumatics Controller PCB flow measurement

10.2 Pneumatics Controller PCB

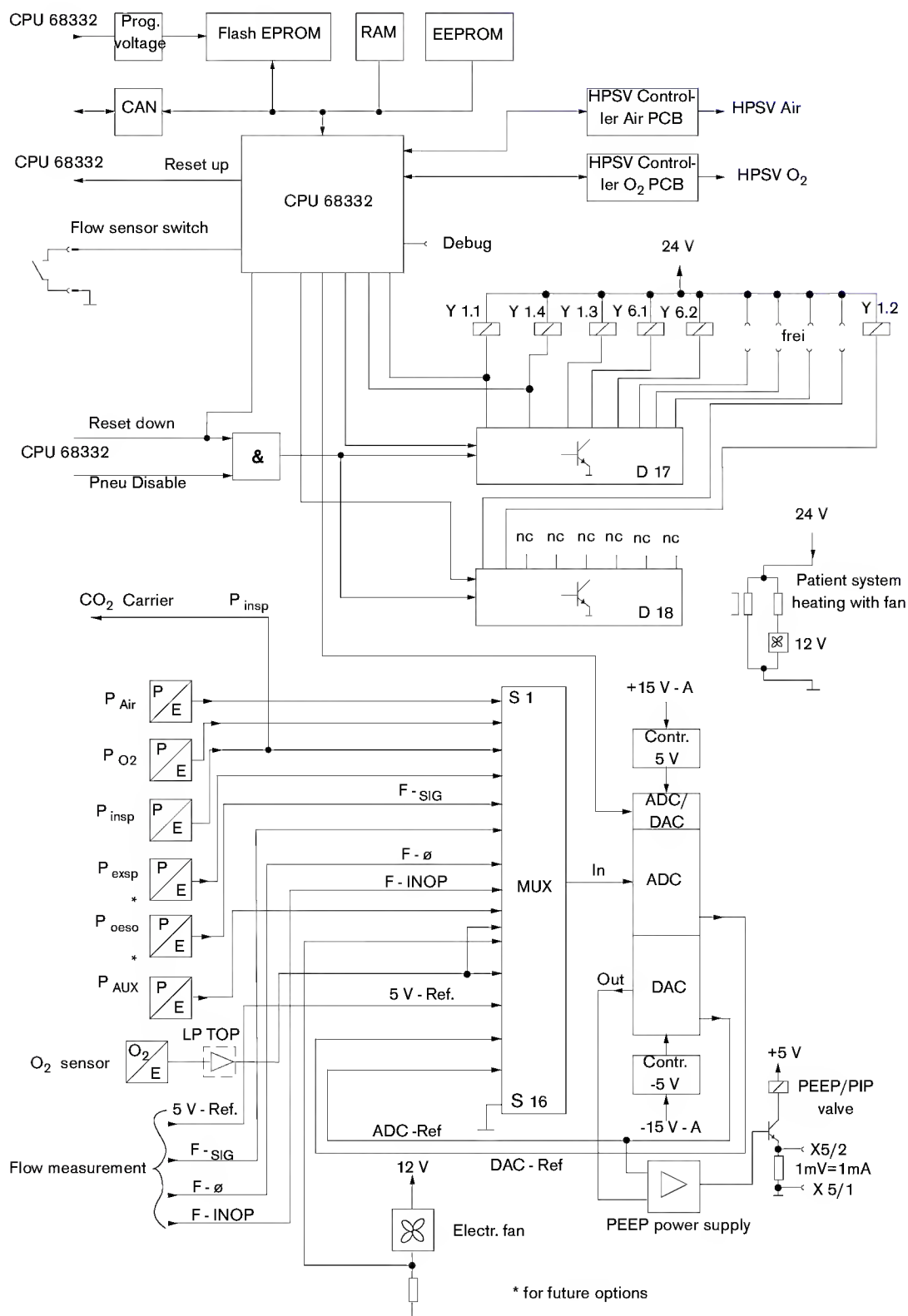


Fig. 19: Pneumatics Controller PCB

10.3 Pressure Measurement

The pressure is measured with two pressure sensors. During the inspiratory phase and the expiratory phase, the pressure is measured by the respective pressure sensor. The airway pressure signals are transmitted to the multiplexer. The pressure sensors are automatically zero-calibrated every 3 minutes.

10.4 Flow Measurement

The sensor works according to the principle of a constant-temperature hot-wire anemometer. Respiratory gas flows along a very thin, electrically heated platinum wire in a measuring tube. The wire is heated to a temperature of 180 °C and kept at this temperature with a closed-loop control system. If gas flows past this wire, heat is dissipated. The larger the gas volume per time unit flowing past, the higher the heat dissipation. The heating power required to keep the wire at a constant temperature is a measure of the gas flow.

10.4.1 Cleaning the Flow Sensor

The control for cleaning or glowing of the sensor supplies a defined current to both measuring wires. During calibration the measuring wires begin to glow and burn any impurities. The sensor is cleaned when pressing the "flow calibration" key or automatically after medicament nebulization. The cleaning process occurs during the next inspiratory phase or after 15 seconds at the latest.

10.5 O₂ Measurement

The O₂ sensor works according to the galvanic cell principle. Oxygen molecules contained in the gas mixture to be measured diffuse through a plastic diaphragm into the electro-chemical cell and are reduced at the noble metal electrodes. At the same time a base electrode is being oxidized. The base electrode is spent by the oxidation process and thus determines the life of a sensor. The current flowing through the cell is proportional to the oxygen partial pressure in the gas mixture to be measured.

Provided the pressure and temperature of the gas mixture to be measured are kept constant, the measured value will be directly proportional to the oxygen partial pressure. The O₂ amplifier on the O₂ Top PCB is mounted externally on the inspiratory block. The output signal is transmitted to the O₂ Contact PCB via spring contacts and transferred to the Pneumatics Controller PCB. The O₂ cell is also connected to the O₂ Top PCB via spring contacts.

10.6 Fan Monitoring

At the front panel of the machine a fan is mounted to limit the temperature and the O₂ concentration in the electronic unit of the pneumatics in case of failure. This fan is monitored by the electronics.

10.7 Multiplexer

The multiplexer consists of 16 analog-value selectors which are controlled by the software. The multiplexer routes the measurement signals from the pressure sensors, the O₂ amplifier, the FAN UREF and the flow sensor to an A/D converter via a buffer.

10.8 Solenoid Valves

The solenoid valves are controlled by two power drivers. The power driver outputs for the nebulizer and the O₂/Air switchover are monitored by a comparator. The power drivers can be switched off by the electronic unit.

10.9 PEEP Valve Control

The PEEP valve is controlled by a voltage-controlled current source with power MOS FET. A quad operational amplifier serves to adapt the D/A converter output signal to the current range of the PEEP valve. The CPU controls the D/A converter. The PEEP valve control is calibrated to the PEEP valve. The calibration data are stored in the serial EEPROM.

10.10 HPSV Interface

The status lines of the HPSV Controller PCB are led to the Pneumatics Controller PCB via the Pneumatics motherboard. Two bus drivers transmit the data to the data bus of the CPU. The data are transmitted to the HPSV Controller PCB by two power drivers. The data are accepted by power swing of the respective Chip-Select-Pins.

10.11 CAN Interface

The CAN interface comprises a CAN controller and a series-connected driver. The CAN controller is directly connected to the data bus of the CPU. The control unit, the electronics and the pneumatics communicate via the CAN interface at a transmission rate of 1 Mbit/s.

10.12 Processor System

The processor system on the Pneumatics Controller PCB consists of a 68332 CPU, a 256 kByte flash EPROM (electrically programmable and erasable read-only memory) and a 256 kByte RAM.

10.13 Serial EEPROM

The serial EEPROM stores the data of the pneumatics. The EEPROM has a 128 Byte capacity.

11 HPSV-Controller PCB

The pneumatics of the Evita 4 contain 2 identical HPSV-Controller PCBs. The board slot determines which of the boards is assigned to O₂ and AIR. The PCB comprises the following functions:

- Microcontroller with EPROM and RAM
- ADC for measurement of supply pressure
- DAC for setpoint entry of current
- Control loop for current control
- Power transistor (power source)
- NOTE: The characteristic of the HPSV cartridge is stored in the cartridge and is read out by the HPSV Controller PCB. The PCB can be replaced without calibration.

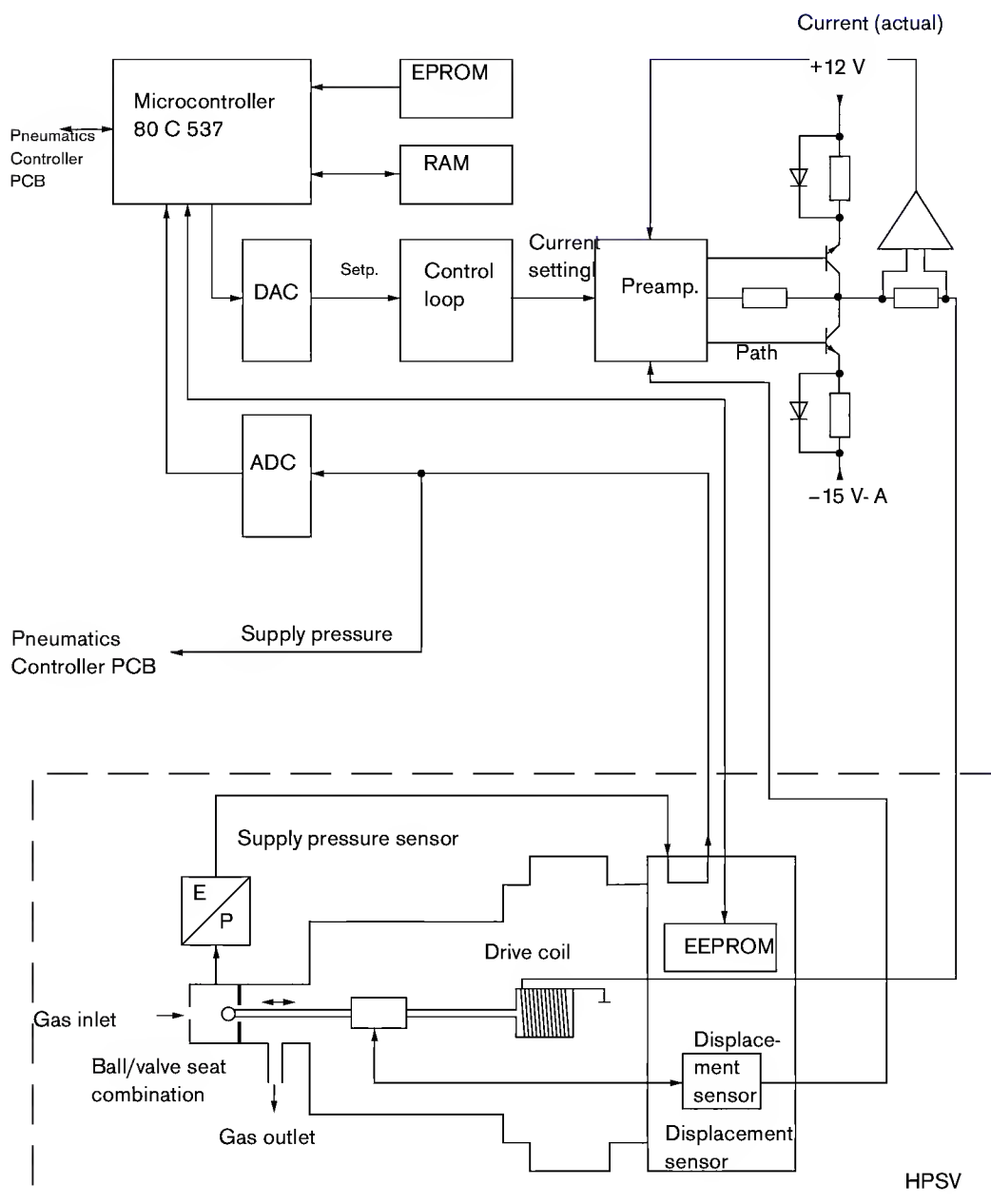


Fig. 20: HPSV Controller PCB with HPSV

12 Frontpanel PCB Evita 2 dura

The Frontpanel PCB is installed in the front panel of the Evita 2 dura. The Frontpanel PCB comprises an independent processor system, the voltage supply to the front panel, the interface to the electronics, and the display control.

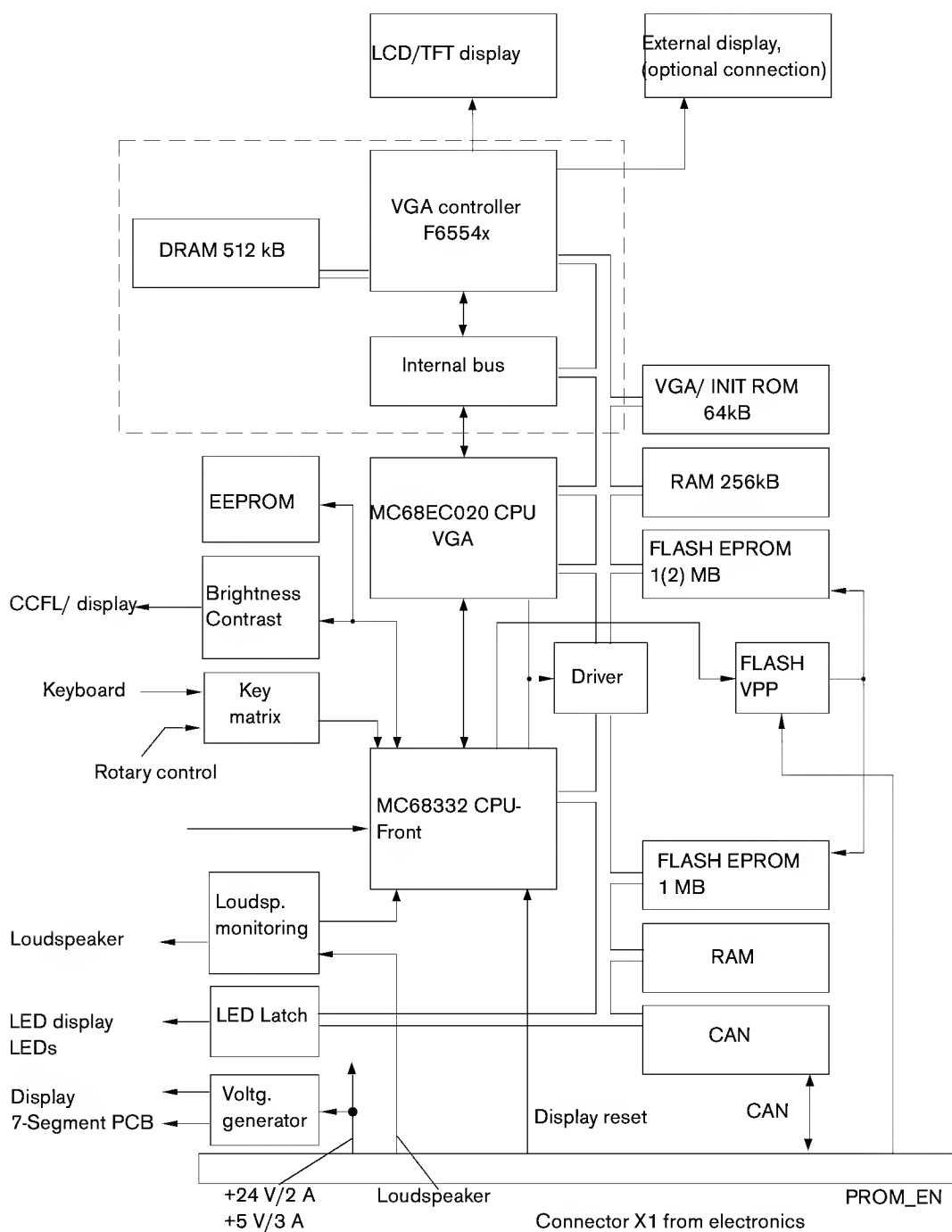


Fig. 21: Block diagram of the Frontpanel PCB

12.1 Processor System

The processor system consists of an MC 68332 and an MC 68EC020 with 256 kilobytes RAM each and 1 Mbyte flash EPROM (electrically programmable and erasable PROM).

12.2 Loudspeaker Monitoring

The loudspeaker monitoring tests the loudspeaker function. The current which flows through the loudspeaker is measured and evaluated with a resistor.

12.3 Keyboard Port and LED Driver

The keyboard is arranged in a 5 x 8 matrix. The 68332 CPU scans the keyboard via the Schmitt trigger. The LEDs are triggered statically via registers.

12.4 Display Control

The MC 68EC020 video processor controls the video processing, generates the synchronous signals for the display, and shows the picture on the display via the VGA controller F6554 x. The video RAM is the memory of the video processor. The size of the video RAMs is 512 kilobytes. The represented picture is stored in the video RAM.

12.5 Flash VPP

The Flash VPP generates the programming voltage for the flash EPROMs. The "PROM_EN" signal and the microcontroller 68332 enable this programming voltage.

12.6 Voltage Generation

The voltage generation uses the +5 V and the +24 V to generate the supply voltage for the display (UBKL +13 V), the contrast voltage for the display ($\pm$ UK approx. 70 V), and the supply voltage for the 7-segment displays (ULED +5 V).

12.7 CAN Interface

The CAN interface is a fast, serial interface (Controller Area Network). The front panel, the electronics, and the pneumatics communicate with each other via the CAN interface. The transmission rate is 1 Mbit/s.

13 7-Segment PCB Evita 2 dura

The 7-Segment PCB controls the 11 triple-groups of the 7-segments displays. Each 7-segment is triggered statically via an 8-bit driver. The 7-segment displays are selected with two "8 from 3" decoders (chipselect generation).

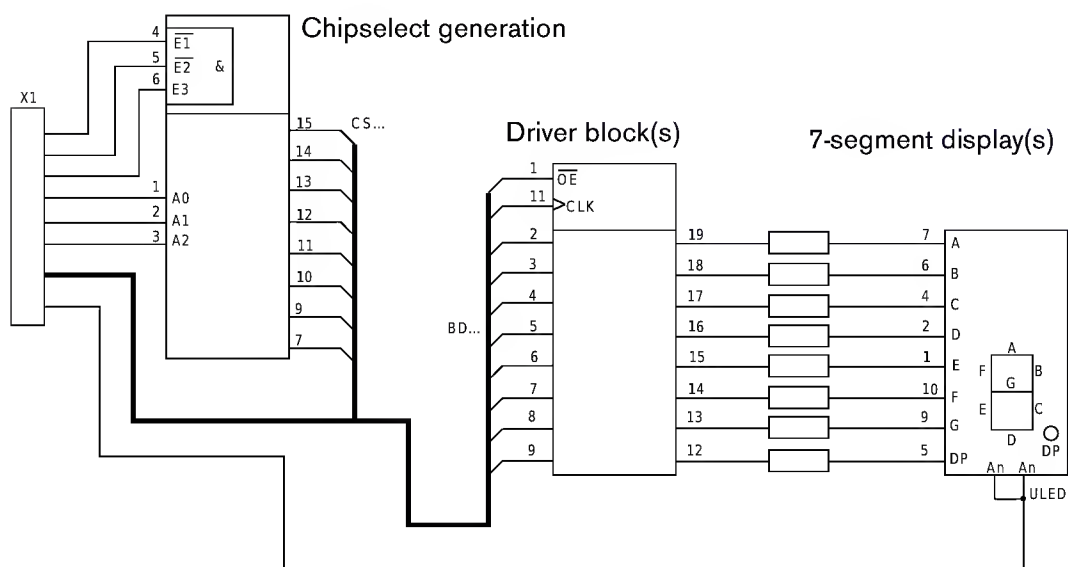


Fig. 22: Block diagram of the 7-Segment PCB

14 Pneumatics

Compressed air (AIR) and compressed oxygen (O₂) must be available at a supply pressure of 2.7 to 6 bar to drive the machine.

The pneumatics consists of the following components:

- Gas connection block
- Parallel mixer or mixer block
- Pressure sensors
- PEEP/PIP valve
- Inspiratory block
- Patient system

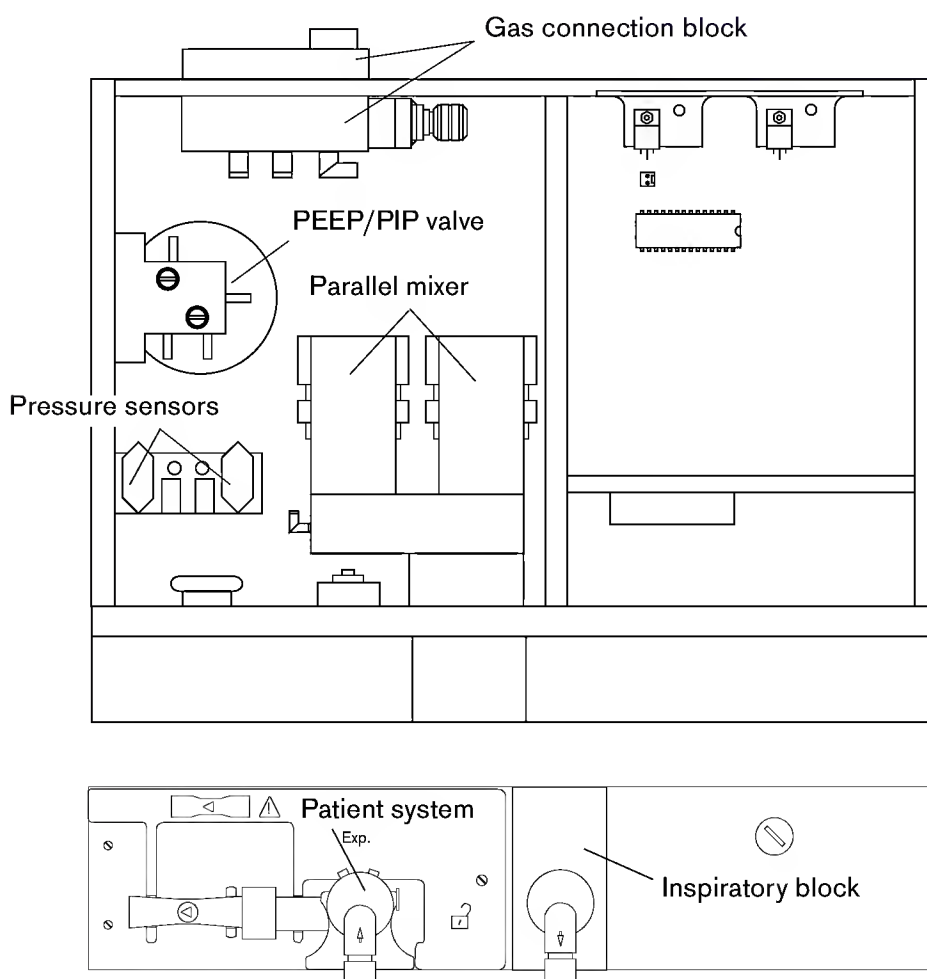


Fig. 23: Layout of the pneumatic components

14.1.1 Characteristics of Various Gas Connection Blocks

Characteristics of the FAS gas connection block:

- connector plate
- pressure regulators

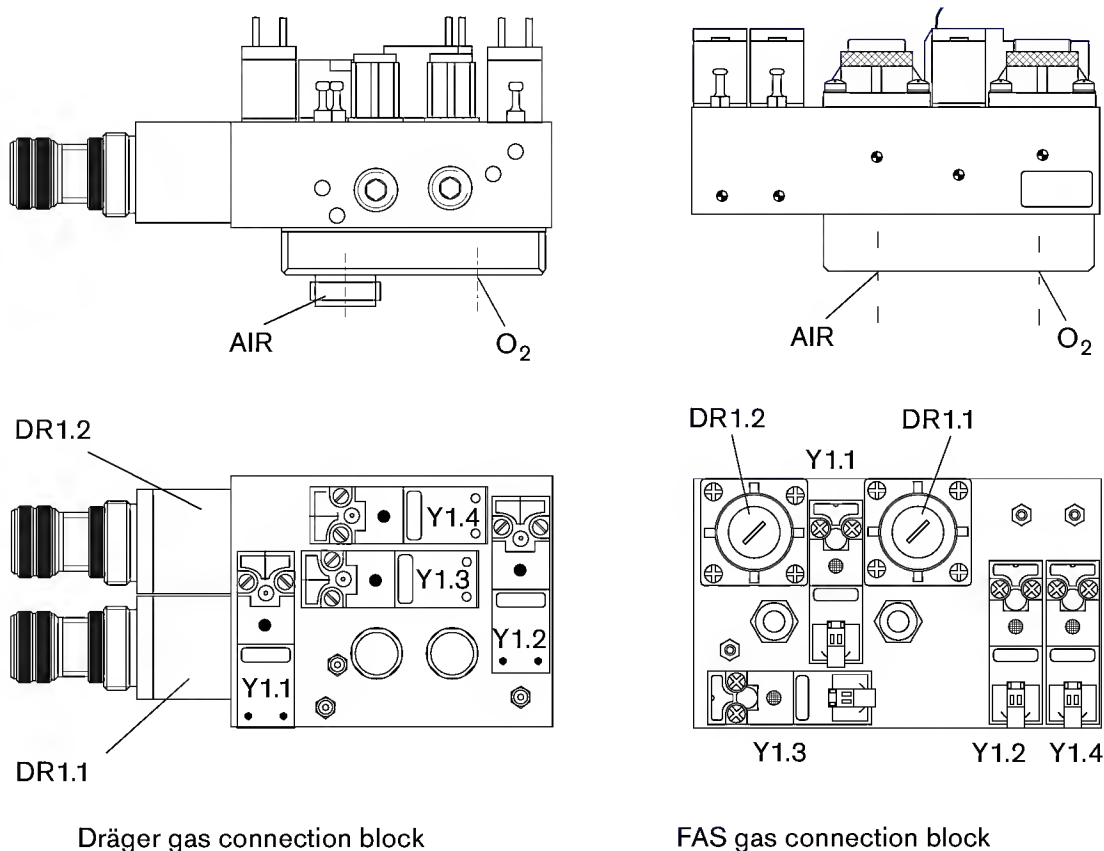


Fig. 25: Dräger gas connection block and FAS gas connection block

Legend

DR1.1 AIR pressure regulator

DR1.2 O₂ pressure regulator

Y1.1 3/2-way solenoid valve, O₂/AIR

Y1.2 3/2-way solenoid valve pressure, sensor calibration inspiration

Y1.3 3/2-way solenoid valve, venting

Y1.4 3/2-way solenoid valve, nebulizer

The gas connection blocks are interchangeable since their mounts for attaching to Evita 4 are identical.

Characteristics of the connector plate on the Dräger gas connection block:

- flat seals
- four fixing screws

Characteristics of the connector plate on the FAS gas connection block:

- O-rings
- two fixing screws

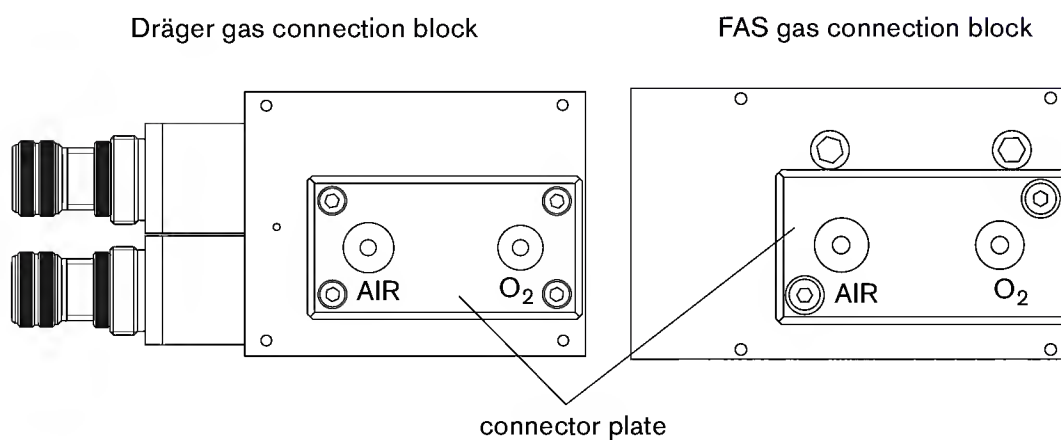


Fig. 26: Connections of the gas connection blocks

14.2 Parallel Mixer or Mixer Unit

The parallel mixer is a fast, electrically controllable proportional valve for gas flows between 5 and 180 L/min at supply pressures of 3 to 6 bar. Partial flows of less than 5 L/min are pulsed at a constant flow of 5 L/min. The supply gases compressed air (AIR) and oxygen (O₂) available at the parallel mixer have a supply pressure of 2.7 bar to 6 bar. In the parallel mixer the two gases are mixed in accordance with the set parameters. The parallel mixer supplies the inspiratory gas to the patient.

The parallel mixer consists of the following components:

- Mixer connection block
- 2 cartridge valves with displacement sensor system for compressed air (AIR) and oxygen (O₂).
- 2 supply pressure sensors measuring the inlet pressure of the supply gases.

The HPSV Controller PCB controls the parallel mixer electrically. The control signals are transmitted to the parallel mixer via the Pneumatics Motherboard PCB and the Pneumatics Controller PCB.

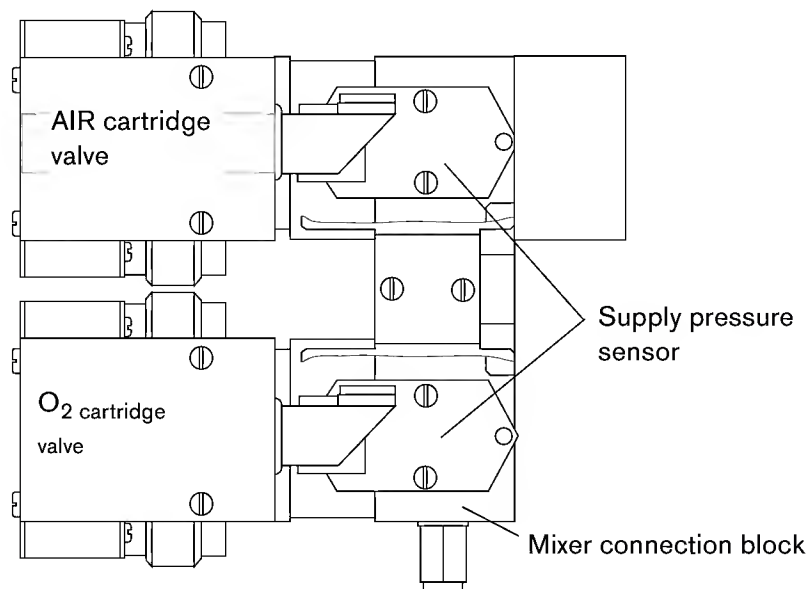


Fig. 27: Parallel mixer

14.3 Mixer Connection Block

The two cartridge valves are mounted to the mixer connection block. The inspiratory gases in the mixer connection block are supplied to the respective cartridge valve. The respiratory gas available at the outlet of the cartridge valves is mixed in the mixer connection block and supplied to the inspiratory unit.

14.4 Cartridge Valves or O₂ and AIR HPS Valves

The cartridge valve or HPS valve (HPSV = high-pressure servo-valve) supplies a defined amount of gas to the patient in accordance with the preset adjustment parameters for e.g. inspiration, trigger pressure, leak flow compensation.

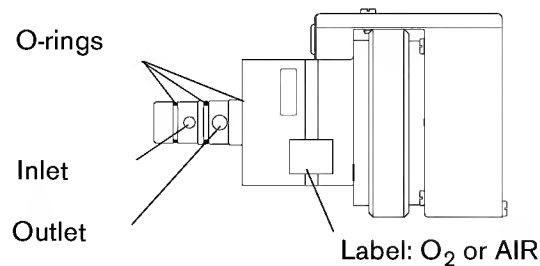


Fig. 28: Cartridge valves or O₂, AIR HPS valves

During expiration the supply gas is available at the cartridge valve and at the supply pressure sensor. In the HPS valve ball A is pressed into the valve seat B. This action closes the valve.

During inspiration, current is supplied to the drive system which is equipped with a coil working according to the principle of a moving coil of the type used e.g. in loudspeakers. The plunger is deflected in proportion to the supplied current and pushes ball A out of valve seat B causing an annular gap. This action opens the cartridge valve and gas flows to the patient.

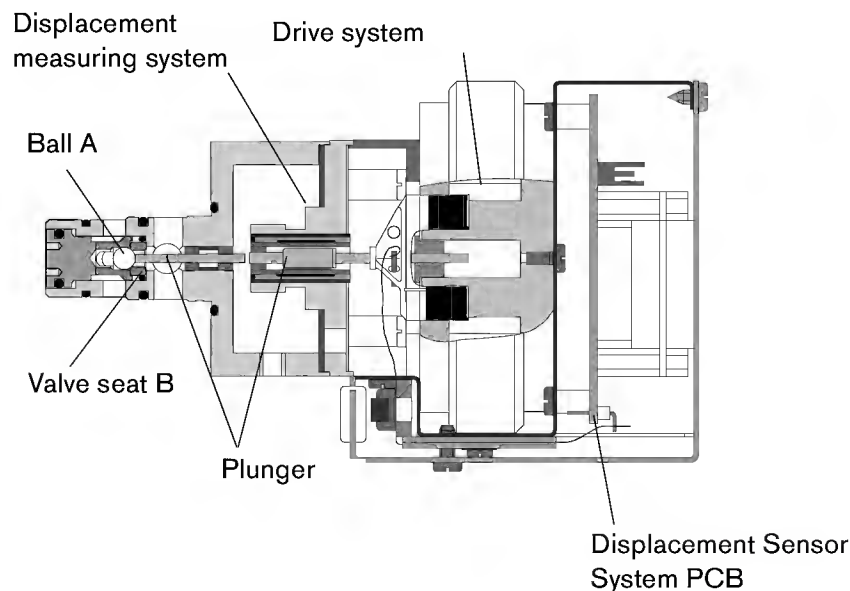


Fig. 29: HPS valve cross-section

Consequently, the size of the annular gap determines the gas flow. The annular gap between the ball and the valve seat is determined by the deflection of the plunger. This deflection is measured and controlled by the displacement measuring system. At the same time a supply pressure sensor at the cartridge valve measures the supply pressure of the gas to be dosed. The supply pressure therefore also determines the gas flow, i.e. twice the pressure for the same width of gap will produce twice the flow.

Width of gap (annular gap) $\uparrow$ or supply pressure $\uparrow$ = gas flow $\uparrow$

The gas flow in valves used to dose and mix the respiratory gas is not measured but determined indirectly by the displacement signal and the supply pressure. The valves supply a flow of 5 – 180 L/min. The plunger movement (displacement) depends on the supply pressure varying between 3–6 bar absolute. For a flow requirement of 120 L/min and a supply pressure of 5 bar the displacement will be approx. 0.2 mm or 0.6 mm for a supply pressure of 1.5 bar.

As the mixer must permanently operate with high precision it is measured and the data (non-linearities) are stored in an EEPROM on the Displacement Sensor PCB. Therefore no calibration is required when the cartridge valves are replaced. The cartridge valves must not be interchanged since they are specifically dimensioned and fitted for each individual gas.

14.4.1 Displacement Sensor System

The displacement sensor system measuring the position of the plunger in the valve is integrated in the cartridge valve and consists of the displacement measuring system and the Displacement Sensor PCB.

The displacement measuring system is a differential transformer. The a.c. voltage applied to the primary winding of the transformer has a frequency of approx. 1 MHz. The two secondary winding are switched such that their output voltage balance out. If the ferrite core (plunger of the cartridge valves) moves in the differential transformer, the output voltage of the displacement sensor system will change.

As the displacement output signal is not linear to the gas flow, the characteristic of the cartridge valves is measured and stored in the EEPROM. The micro-controller on the HPSV PCB thus balances the non-linearity of the cartridge valves.

The two circuits of the cartridge valves of parallel mixers are operated asynchronously in parallel (AIR, O₂). To avoid beat interferences, the frequencies of the two oscillators must differ by a minimum of 200 kHz. To do so, the two cartridge valves are measured at two different frequencies. The cartridge valves can only be measured at a special test stand.

14.4.2 Supply Pressure Sensors

The supply pressure sensors are calibrated to absolute pressure (0 bar). They measure the inlet pressure of the supplied gas. The supply pressure sensor is fitted with a P/U converter supplying a pressure-dependent output pressure.

Measuring range: 0–7 bar
Sensitivity: 1.58 V/bar $\pm$ 8 mV/bar
Offset voltage: 300 mV $\pm$ 30 mV

The supply pressure sensors are linked via a flex-strip to the Displacement Sensor PCB which is installed in the HPS valves.

14.5 Pressure Sensors

The pressure sensor mount comprises the airway pressure sensors S6.1 for the inspiratory side and S6.2 for the expiratory side. S6.1 monitors the inspiratory P_{aw} high and P_{aw} low.

Measuring range: 140 mbar
Sensitivity: 36.5 mV/mbar $\pm$ 0.3 mV/mbar
Offset voltage: 1.74 V $\pm$ 0.04 V

14.5.1 Pressure Sensor Calibration

The solenoid valves Y6.1 and Y6.2 expose the relevant pressure sensors to atmospheric pressure at specific time intervals. Consequently, the sensors are automatically calibrated. The pressure sensors S6.1 and S6.2 are zero-calibrated every 3 minutes (calibration of the possible electronic zero drift). To do so, the solenoid valves Y6.1 and Y6.2 are subsequently exposed to atmospheric pressure and the pressure sensors automatically calibrated.

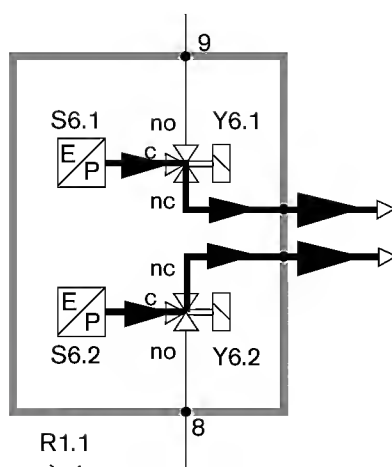


Fig. 30: Pressure sensors function diagram

14.6 Inspiratory Unit

The safety valve D3.3 limits the pressure in the inspiratory line to 100 mbar max.

In the event of compressed air failure or power failure the pneumatically controlled emergency air valve Y3.1 will open so that the patient can breathe ambient air passing the filter F3.1. The check valve D3.1 prevents rebreathing of the air through the inspiratory line. The spring-loaded check valve D3.2 allows pressure to drop if valve Y3.1 opens.

In the case of emergency air spontaneous breathing the patient can expire through the expiratory valve Y5.1 on account of the spring loading (5 mbar) thus preventing rebreathing.

The inspiratory unit is provided with the plug-in connection for the oxygen sensor.

The restrictor R1.2 limits the medicament nebulizer flow to 9 L/min.

14.6.1 Emergency Air

In the event of a gas or power supply failure the patient can breathe spontaneously via filter F3.1. The emergency air valve Y3.1 will in this case no longer be controlled. The patient can breathe spontaneously via filter F3.1, check valve D3.1 and the emergency air valve Y3.1.

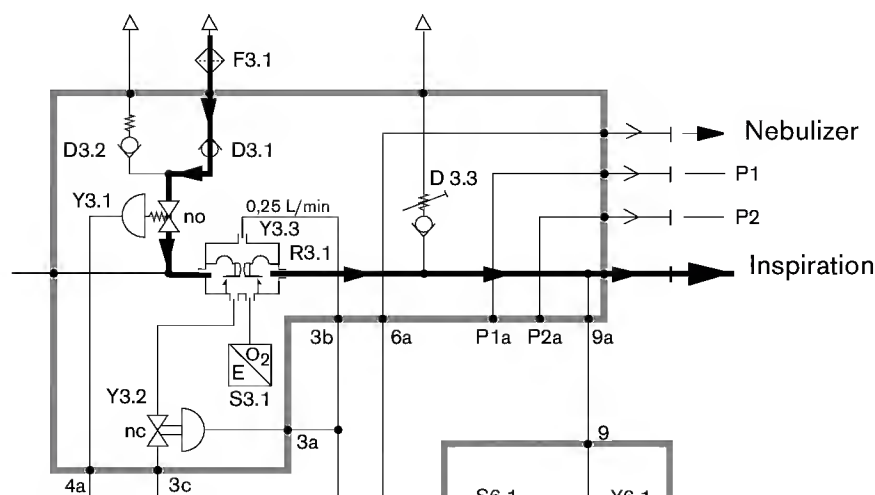


Fig. 31: Emergency air function diagram

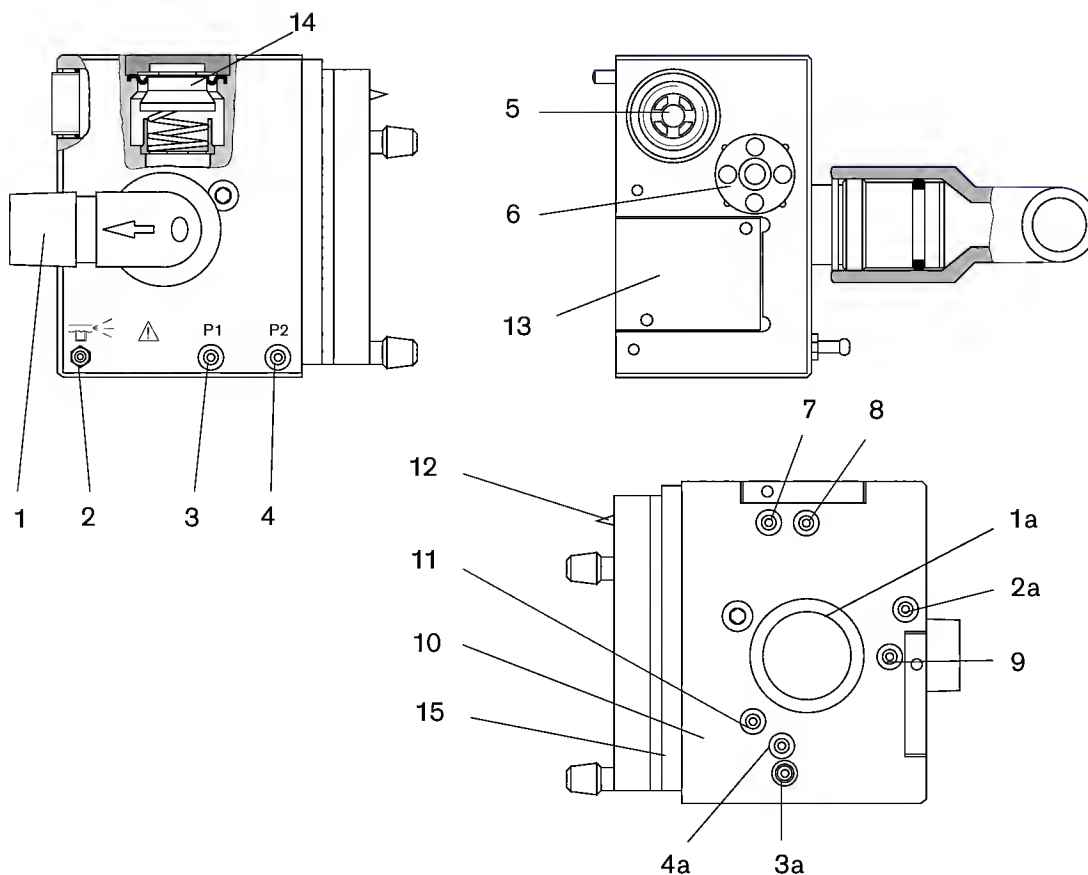


Fig. 32: Inspiratory unit

Legend

- 1-1a Patient connection (inspiration)
- 2-2a Nebulizer connection
- 3-3a Oesophageal pressure P1
- 4-4a Oesophageal pressure P2
- 5 10 mbar pressure relief valve
- 6 100 mbar pressure relief valve (adjustable; NOTE: until middle of '96 valve slot milled in the block, after '96 separate piece screwed onto the block)
- 7 Emergency pressure relief mechanism control
- 8 Pressure measurement (inspiration)
- 9 O₂ calibration control
- 10 O₂ sensor chamber (behind the O₂ booster)
- 11 O₂ calibration purge flow outlet
- 12 Emergency air check valve D3.1 in O₂ booster
- 13 O₂ calibration diaphragm lattice Y3.3 with R3.1
- 14 Valve Y3.1
- 15 O₂ booster

14.7 Patient System

The expiratory gas flows from the patient directly to the expiratory valve Y5.1. The copper measuring line at the 8a connection has a germicidal effect and connects the expiratory side to the pressure sensor S6.2.

The expiratory valve has a transmission ratio of approx. 1:1. The check valve D5.1 allows flow in one direction only and makes sure that gases do not travel backwards. The expiratory flow is measured with flow sensor S5.1.

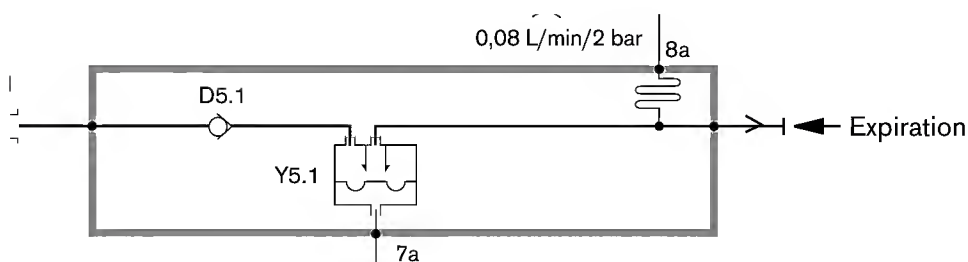


Fig. 33: Patient system function diagram

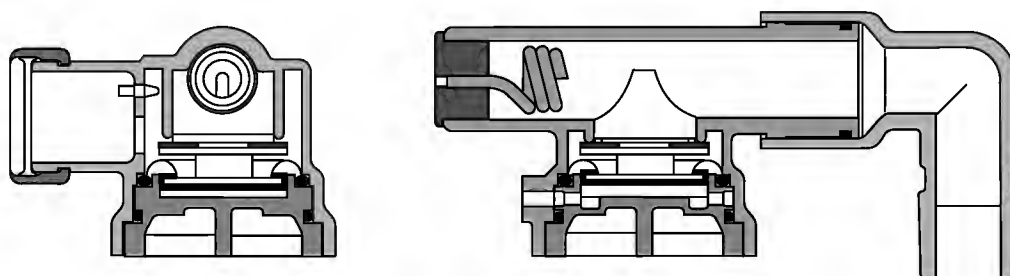


Fig. 34: Patient system cross-section

The ratio between the control pressure at the 7a connection of the PEEP/PIP valve and the resulting pressure at the expiratory port is linear to the following values:

Control pressure of 3 mbar $\Rightarrow$ expiratory pressure of 0 mbar

Control pressure of 33 mbar $\Rightarrow$ expiratory pressure of 33 mbar

14.7.1 Patient System with Water Trap

The water trap avoids flow measurement faults caused by water droplets. Such faults may occur if the water traps on the ventilation hoses are not positioned at the lowest possible point. In this case the condensation water is collected in the water trap of the patient system.

The collector jar of the water trap can be removed during operation. The opening to the patient system is sealed automatically.

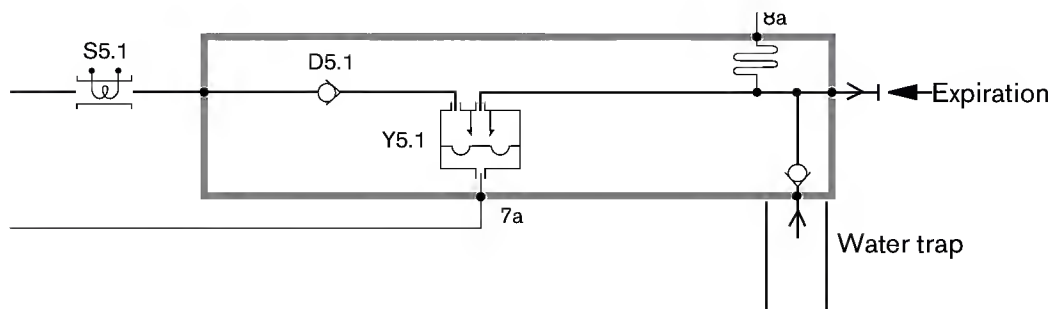


Fig. 35: Function diagram of the patient system with water trap

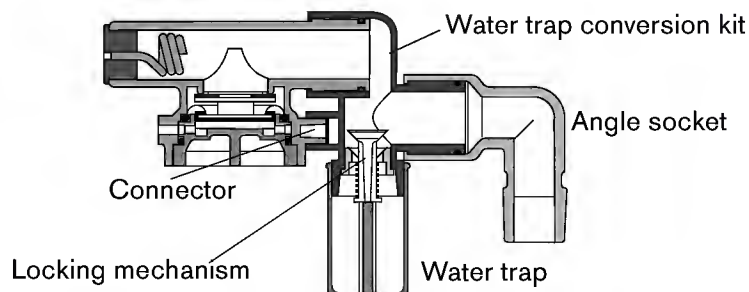


Fig. 36: Sectional view of the patient system with water trap

14.8 PEEP/PIP Valve

The PEEP valve Y4.1 consists of a diaphragm valve acting as a flow-control device and the linear drive whose plunger closes the diaphragm valve. A coil drives the PEEP valve Y4.1. The preset ventilation parameters are processed by a computer program and the coil is driven by an appropriate current. The PEEP valve opens and adjusts a pressure proportional to the adjusted electric current. A current of 0 mA will correspond to -1 mbar, 600 mA to 120 mbar.

A servo-line in the valve Y4.1 controls the expiratory valve Y5.1 in the patient system. The solenoid valve Y1.3 and the restrictor R4.1 supplies the patient system with control gas. The non-adjustable restrictor R4.1 is set to a flow of 3.5 L/min.

Depending on the setting the plunger coil is activated causing an appropriate servo-pressure to be applied to the expiratory valve.

The software compares the preset and measured airway pressures. This comparison is a measure of the Pneumatic-Controller PCB's control action on the PEEP/PIN valve. The PEEP/PIN valve is calibrated to the electronics. The calibration data are stored on the Pneumatic-Controller PCB.

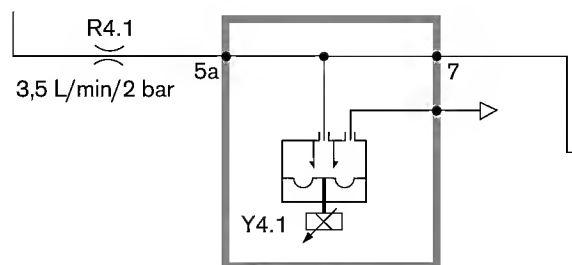


Fig. 37: PEEP valve function diagram

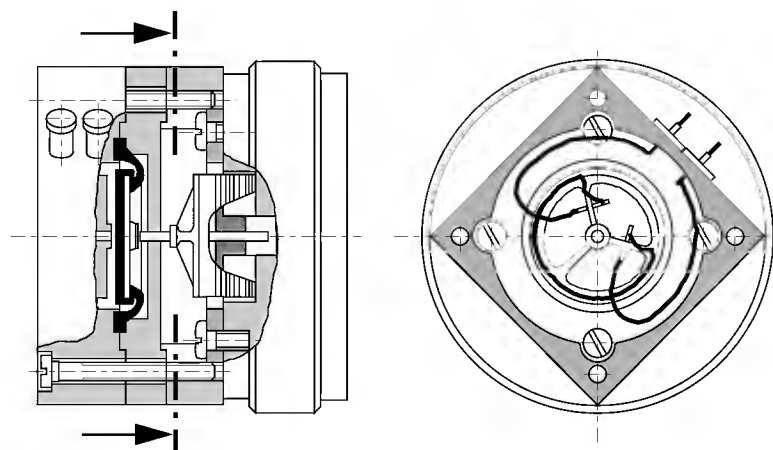


Fig. 38: PEEP valve cross-section

14.9 AIR Supply

AIR flows through the filter F1.1 passing the check valve D1.1 reaching the mixer and flow control unit (pressure sensor S2.1 and HPSV Y2.1). At the same time, AIR flows to the 3/2-way solenoid valve Y1.1 passing the pressure regulator DR1.1 which is set to 2 bar. From here the gas flows through the 3/2-way solenoid valve Y1.3 to the emergency air valve Y3.1 which closes. Furthermore, AIR passes the restrictor R4.1 to reach the PEEP/PIP valve Y4.1 and from there – depending on the setting – to the expiratory valve Y5.1. Finally, AIR passes the restrictor R1.1 to flow to the expiratory pressure sensor S6.2 connecting line on the patient side. At this point, expiratory humidity is prevented from reaching the pressure sensor S6.2.

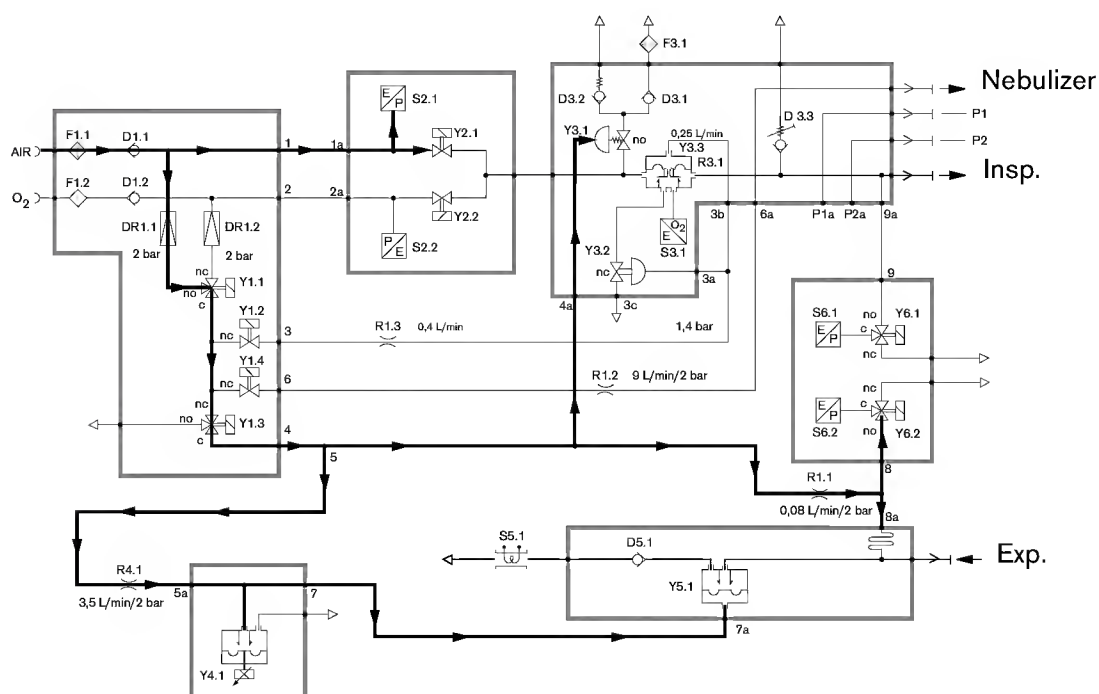


Fig. 39: AIR supply function diagram

Compressed oxygen flows through the filter F1.2 via the check valve D1.2 to the mixer and flow control unit (pressure sensor S2.2 and HPSV Y2.2). At the same time, O₂ flows to the 3/2-way solenoid valve Y1.1 via the pressure regulator which is set to 2 bar.

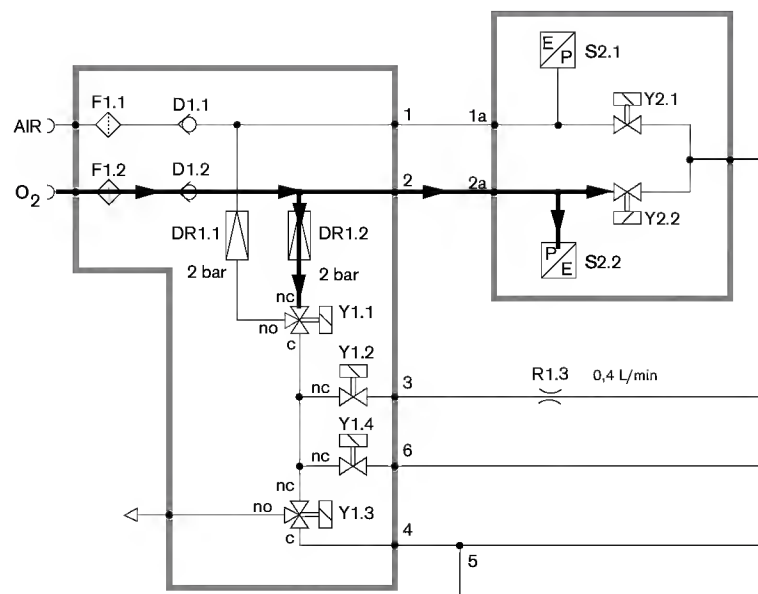


Fig. 40: O₂ supply function diagram

In the event that compressed air fails, in the course of O₂ sensor calibration and when controlling the nebulizer function (depending on the FiO₂ setting) the 3/2-way solenoid valve Y1.1 switches over. The servo-system will then be supplied with O₂.

14.11 Inspiration

Depending on the settings (O_2 concentration, inspiratory volume, frequency, T_I , inspiratory flow, inspiratory pressure) the HPSVs Y2.1 and Y2.2 open. The gas flows via the inspiratory connector to the patient. At the same time, gas flows to the O_2 sensor S3.1 and to the safety valve D3.3. From there, it flows through the 3/2-way solenoid valve Y6.1 to the inspiratory pressure sensor S6.1.

The safety valve D3.3 is fixed to 100 mbar and serves as an additional safety device in the event of a complete failure of the electronic control.

When calibrating the O_2 sensor S3.1 the sensor will be disconnected with valve Y3.3 from the inspiratory gas. The O_2 sensor S3.1 is purged with calibration gas via valve Y1.2, the restrictor R1.3, the restrictor R3.1 and the valve Y3.2. The O_2 concentration and the flow will not be influenced by the inspiratory gas.

The pressure sensors S6.1 and S6.2 monitor the inspiratory pressure. During the entire inspiratory time the PEEP/PIP valve Y4.1 provides pressure to the expiratory valve Y5.1.

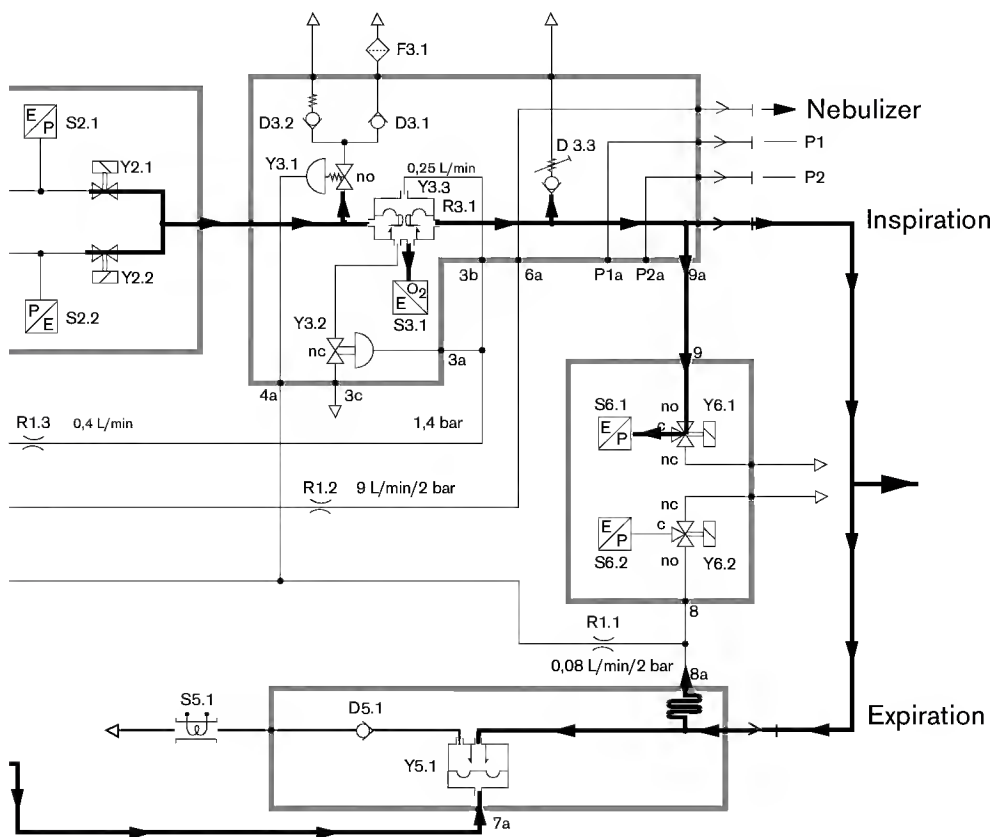


Fig. 41: Inspiration function diagram

14.12 P_{aw} High

In case the P_{aw} high alarm limit is exceeded during inspiration, the HPSV Y2.1 and Y2.2 interrupt the gas flow. The PEEP/PIP valve Y4.1 is switched to expiration and the patient can exhale.

14.13 Emergency Pressure Relief Mechanism

In case the P_{aw} high alarm limit is exceeded by 5 mbar, an additional pressure relief valve Y1.3 will open. This will cause the emergency air valve Y3.1 to open and the pressure can additionally be reduced via check valve D3.2.

14.14 Expiration

At the start of expiration the HPSV Y2.1 and Y2.2 are closed and no gas will be supplied to the patient. The PEEP/PIP valve Y4.1 is switched to the set PEEP value. The expiratory valve Y5.1 will also be relieved and the patient can exhale via check valve D5.1 and the flow sensor S5.1. The flow sensor S5.1 measures the expiratory volume.

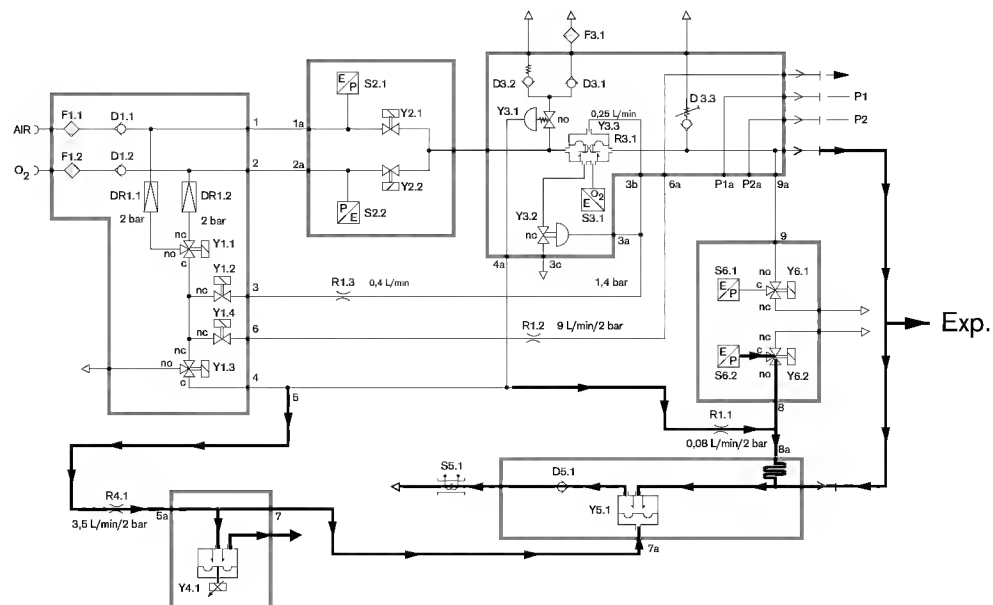


Fig. 42: Expiration function diagram

15 Ventilation Modes

15.1 Volume-Controlled Ventilation with PLV and Auto-Flow

Auto-Flow is a new feature optimizing the flow control during the mandatory breath in the constant-volume ventilation modes IPPV, SIMV and MMV. To understand the differences you will find below an explanation of the conventional functions.

15.2 Classic Constant-Volume Mandatory Breath

In mandatory breaths without Auto-Flow the “insp. flow” parameter limits the inspiratory flow. If the inspiratory flow is so high that the set tidal volume V_T is attained prior to the end of the inspiratory time T_{insp} , the inspiratory valve will close and the supply of breathing gas will cease. The expiratory valve will remain closed until the inspiratory time T_{insp} has ended. This phase, also referred to as the inspiratory pause, can be seen as plateau pressure P_{plat} in the $P_{\text{aw(t)}}$ waveform.

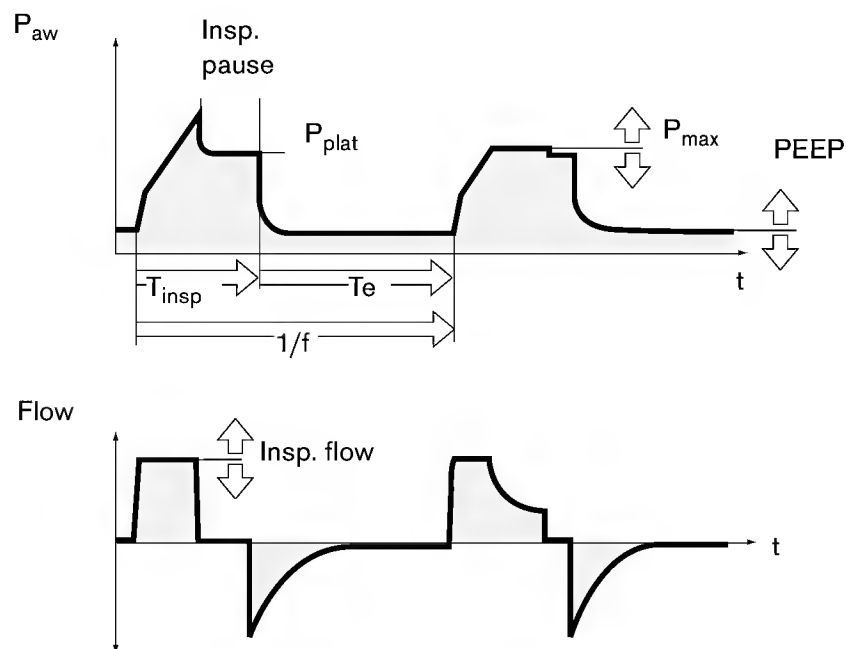


Fig. 43: IPPV waveform

This type of mandatory breaths found in virtually all intensive care ventilators for technical reasons has two important disadvantages:

- The pressure peak can lead to overinflation of individual pulmonary areas in inhomogeneous lungs, and
- the limited inspiratory flow and the inspiratory and expiratory valves closed during the inspiratory pause will cause the patient to work against the machine unless the respiratory pattern is regularly adapted to the requirements of the spontaneously breathing patient.

15.3 Manual Pressure Limitation $P_{\max}$

The $P_{\max}$ pressure limitation function in Evita 4 serves to avoid the pressure peak while maintaining the set tidal volume V_T . The tidal volume V_T remains constant as long as a pressure plateau P_{plat} can still be recognized and the flow waveform still shows a short zero flow between inspiration and expiration.

Evita 4 meets this requirement by reducing the inspiratory flow as soon as the $P_{\max}$ setting has been attained. In the event that the tidal volume V_T at the preset pressure $P_{\max}$ can no longer be applied due to a reduced compliance, an "inconstant volume" alarm will automatically be given. The manual pressure limitation function is available on all units of the Evita 4 series.

15.4 Auto-Flow

The Auto-Flow function can be activated from the "Extended Settings" menu. Auto-Flow ensures adjustment of the inspiratory flow and Pmax parameters as the relevant adjusting knobs no longer appear on the "Settings" menu.

The inspiratory flow automatically adapts to the changes of the pulmonary conditions (C, R) and the respiratory requirements of the patient.

IMPORTANT:

Make sure to always set the " P_{aw}/T " alarm limit so that an alarm will be given as soon as the airway pressure increases while the patient's compliance is reduced.

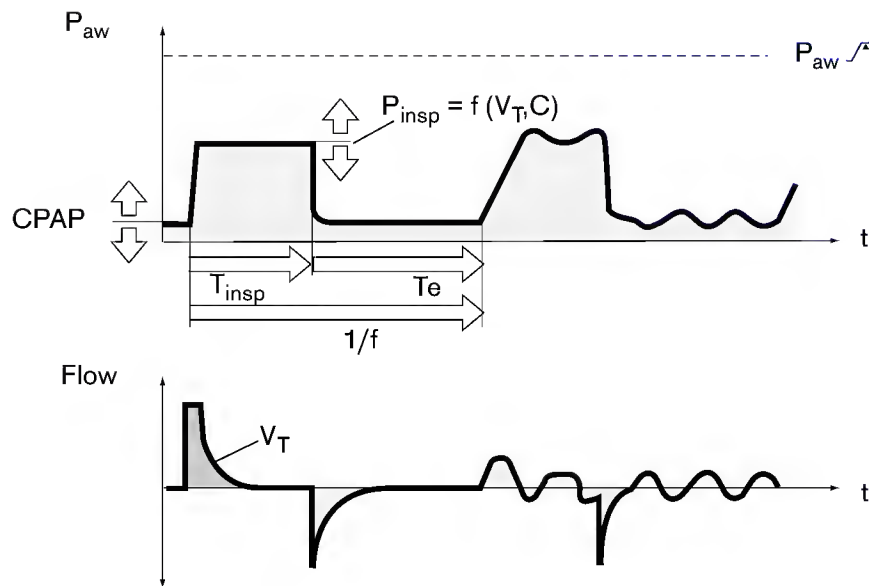


Fig. 44: Auto-Flow waveform

The selected inspiratory time T_{insp} is typically much longer than the filling phase of the lungs. The inspiratory pressure P_{insp} is equivalent to the minimum value resulting from the tidal volume V_T and the lungs' compliance C .

The inspiratory flow is automatically controlled to avoid any pressure peaks which may result from the tube and airway resistances. The plateau pressure P_{plat} changes with the compliance C changing, which is common in constant-volume respiratory breaths. In the Auto-Flow mode these changes occur in steps of 3 mbar max. from one breath to another.

When the tidal volume V_T is attained (inspiratory flow = 0) before the inspiratory time T_{insp} has expired, the control of the inspiratory and expiratory valves ensures that the patient can inspire and expire during the remaining inspiratory time even if the plateau pressure P_{plat} remains constant.

If the patient inspires or expires during mandatory inspiration, the plateau pressure will not change but the inspiratory and expiratory flows will adapt to the patient's demand. It may occur that the individually applied tidal volume in some breaths differs from the adjusted tidal volume. However, on the average the tidal volume V_T applied will be constant.

Exceeding of the tidal volume V_T can be limited with the " V_{Ti} / f " alarm limit. When the set alarm limit is exceeded for the first time, the Evita 4 will give a message (!). In case the limit is exceeded three times in a row an alarm (!!!) will be given. If necessary, the volume can be limited to the " V_{Ti} / f " alarm limit by switching to the PEEP level.

The flow waveform indicates if the set inspiratory time T_{insp} is shorter than the filling time of the lungs, i.e. at the end of the inspiratory time the flow will not yet be zero. In this case a decision must be taken if the current condition of the patient allows extending the inspiratory time T_{insp} in order to lower the peak pressure further.

This effect may also be caused during ventilation, e.g. by congestion of secretions. In this situation the „ $P_{aw} \nearrow$ “ alarm limit limits the pressure. The pressure increase stops at a level 5 mbar below the „ $P_{aw} \nearrow$ “ alarm limit and the “inconstant volume” alarm will only be activated if the set tidal volume V_T is no longer applied.

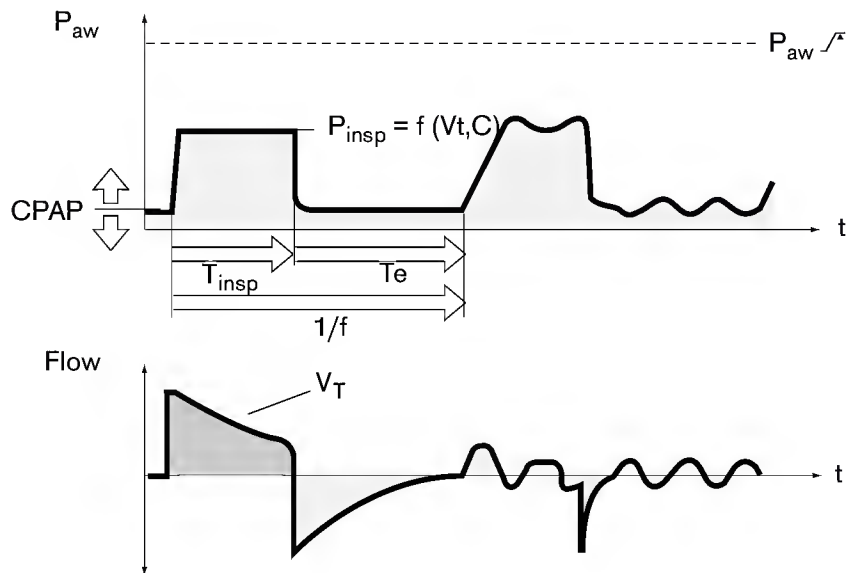


Fig. 45: Auto-Flow waveform

It is possible to synchronize the start of the mandatory inspiration with the patient's spontaneous respiratory effort using the variable flow trigger. The flow trigger can only be completely turned off in the IPPV mode (IPPVpAssistp→pIPPV).

Furthermore, it is possible to adapt the rate of pressure increase from PEEP level to the inspiratory level even better to the patient's requirements with the „ $\nearrow$ “ pressure increase time ventilation parameter in the SIMV and MMV modes.

15.4.1 Starting Performance in Auto-Flow

When starting the Auto-Flow function Evita 4 applies a constant-volume breath with a subsequent inspiratory pause. The plateau pressure calculated for this breath serves as a starting value for the inspiratory pressure in the Auto-Flow function.

15.5 Artificial Sighs

An artificial sigh is an intermittent PEEP in the IPPV, IPPV Assist and ILV ventilation modes.

The expiratory sigh during ventilation is designed to open collapsed pulmonary areas or to keep “slow” pulmonary areas open.

Since atelectatic alveoli have a higher time constant i.a. due to stenosed bronchioli, it is necessary that the airway pressure is higher for a longer period of time to open the bronchioli.

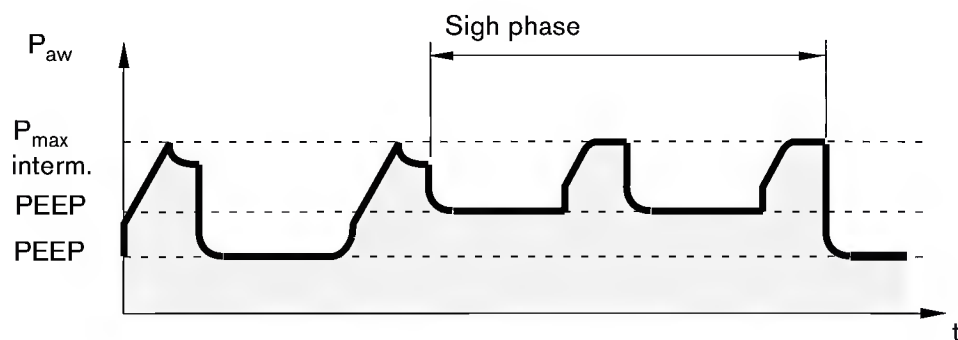


Fig. 46: Sigh waveform

The sigh function is often achieved by increasing the ventilatory breath. However, as only little time is available the “slow” alveoli will not fill much more easily.

In Evita 4 the artificial sigh is an intermittent PEEP during expiration.

The average airway pressure is higher, and normally the available filling time is longer.

In order to avoid overinflation of the lungs, the pressure peaks during the sigh phase can be limited using the P_{max} pressure limitation function without reducing the efficiency of the sigh function.

The “inconstant volume” alarm is not activated during the sigh phase.

15.6 SIMV (Synchronized Intermittent Mandatory Ventilation)

SIMV is a mixed ventilation mode combining mechanical ventilation and spontaneous breathing.

In the SIMV mode, the patient can breathe spontaneously at specified regular intervals while mandatory breaths provided by the machine ensure a minimum amount of ventilation. This minimum ventilation is defined by two ventilation parameters, i.e. the tidal volume V_T and the frequency f and is the result of $V_T \times f$.

The ventilation pattern is defined by the settings for the tidal volume V_T , the inspiratory flow, the frequency f and the inspiratory time T_{insp} . To avoid that the mandatory breath is applied during spontaneous expiration, the machine's flow trigger ensures that a mandatory breath is synchronized with the patient's spontaneous inspiration within a "trigger window".

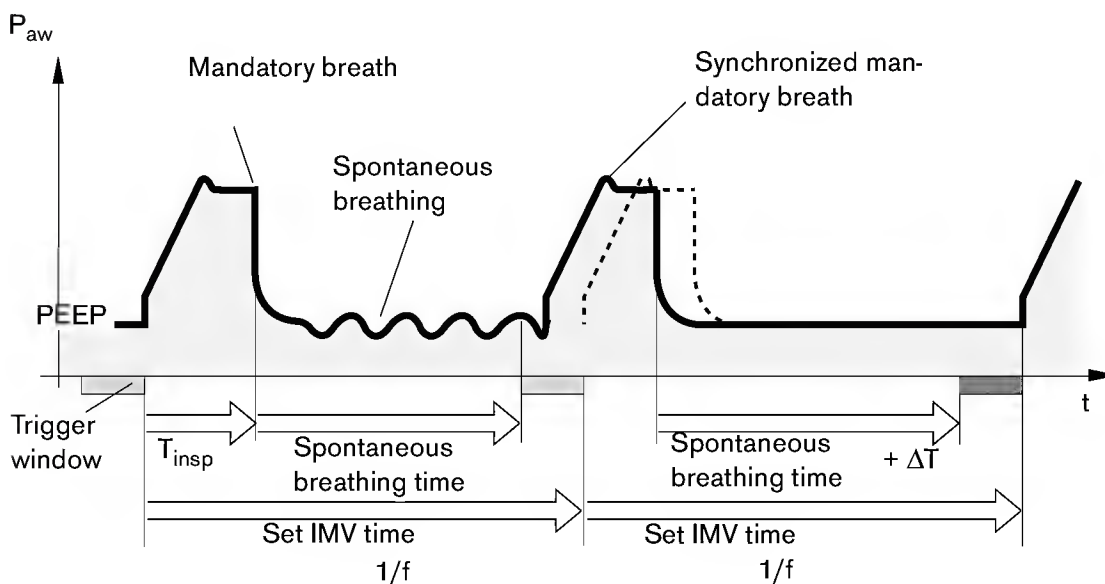


Fig. 47: SIMV waveform

The "trigger window" lasts 5 seconds and thus over the entire expiratory time if this is less than 5 seconds.

Since the synchronization of the mandatory breath reduces the effective SIMV time thus increasing the effective frequency, Evita 4 extends the subsequent spontaneous breathing time by the missing time difference ΔT . Consequently, the SIMV frequency will not become too high. The second factor determining the minimum ventilation, namely the frequency f , remains unchanged. Once the patient has inspired a considerable volume at the start of the trigger window, the machine reduces the subsequent mandatory breath by decreasing the inspiratory flow phase and the inspiratory time. The tidal volume V_T remains constant and overinflation of the lungs is avoided.

During spontaneous breathing the patient will receive pressure assistance (ASB).

In the course of weaning the patient from the ventilator the frequency f is reduced further thus extending the spontaneous breathing time until the required minute volume is completely covered by spontaneous breathing.

15.7 ASB (Assisted Spontaneous Breathing)

ASB is used to supply pressure support if spontaneous breathing is insufficient.

The machine supports the patient's insufficient spontaneous breathing effort in a similar way as the anaesthetist does when he or she observes the patient's recurring spontaneous breathing on the breathing bag and supports it by squeezing the bag.

The machine assumes part of the inspiratory work while the patient keeps control over his or her spontaneous breathing.

The CPAP system supplies breathing gas to the spontaneously breathing patient irrespective of how strong or weak his or her breathing effort may be.

The ASB pressure support will be activated

- when the spontaneous inspiratory flow has attained the set flow trigger value, or
- when the spontaneously inspired volume exceeds 25 mL (or 12 mL in paediatric application).

The machine will in this case increase the pressure to the preset ASB pressure (P_{ASB}) which has been adapted to the patient's respiratory requirements.

The time for the pressure increase can be adjusted from 64 ms up to 2 s.

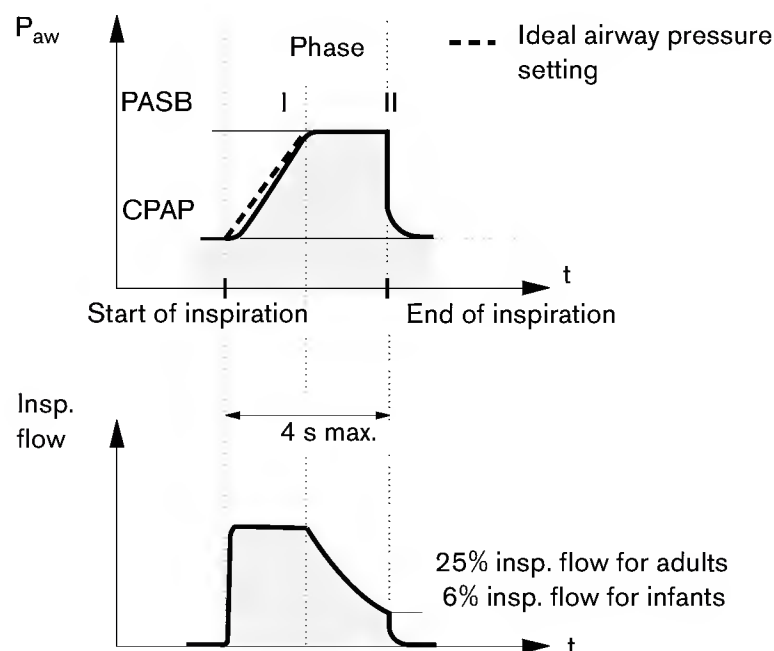


Fig. 48: ASB waveform

Evita 4 supports the patient's insufficient spontaneous breathing with a high peak flow in the ASB mode with fast pressure increase $\nearrow$.

In the ASB mode with slow pressure increase $\nearrow$ Evita 4 supplies a uniform inspiratory flow. The patient has to do more work of breathing so that the respiratory muscles have to exercise.

In the ASB mode with adapted pressure increase $\nearrow$ and ASB pressure P_{ASB} the patient determines the required inspiratory flow with his or her breathing activity. The flow may rise to 2 L/s within 8 ms.

ASB is terminated

- when the inspiratory flow drops to 0 in phase I, i.e. when the patient exhales or breathes against the machine, or
- when the inspiratory flow in phase II falls by a certain ratio below the maximum value supplied before:
ventilation of adults: 25% inspiratory flow; ventilation of infants: 6% inspiratory flow; or
- at the latest after 4 seconds (or 1.5 seconds in paediatric application) provided the two other criteria did not apply. If the time criterion applies three times in a row, Evita 4 will give an alarm that the breathing system may be leaky.

15.8 BIPAP (Biphasic Intermittent Positive Airway Pressure)

BIPAP is a pressure/time-cycled ventilation mode in which the patient can always breathe spontaneously. BIPAP is therefore also often described as time-controlled change between two CPAP levels.

The time-controlled pressure change ensures controlled ventilation equivalent to the pressure-controlled ventilation mode PCV. As spontaneous breathing is permanently possible, however, the change-over from controlled ventilation to weaning and eventually completely spontaneous breathing is smooth so that there is no need to switch from one ventilation mode to another. To adapt the ventilation to the spontaneous breathing behaviour of the patient the change from the expiratory pressure level to the inspiratory pressure level and vice versa is synchronized with the patient's spontaneous breathing.

The frequency of the change-over is also kept constant during synchronization by the trigger windows.

As recent clinical experience has shown, this way of adapting ventilation to the patient's spontaneous breathing activity requires less sedation thus enabling the patient to return to spontaneous breathing at a much faster rate.

As in all pressure-controlled ventilation modes the tidal volume delivered to the patient is not fixed but results primarily from the difference in pressure between the PEEP and P_{insp} settings.

The tidal volume will change if the lung compliance and the airways change or if the patient breathes against the machine.

Knowing that the tidal volume and consequently the minute volume will not always be constant, the user has to make sure that the minute volume alarm limits are properly adjusted.

The required difference in the two pressure levels is adjusted on the basis of the expiratorily measured tidal volume V_{T_e} displayed. Increasing the difference causes a higher BIPAP breath.

15.8.1 Applying BIPAP

As in IPPV, the time pattern is adjusted with the parameters of the basic frequency and $T_I:T_E$ ratio settings. Evita 4 calculates the inspiratory and expiratory times and displays the results on the bottom screen below the waveform setting. The lower pressure level is adjusted with the PEEP parameter, the upper pressure level with the P_{insp} parameter. When switching from IPPV to BIPAP, only the $P_{\text{max}}/P_{\text{insp}}$ needs to be changed while the time pattern remains unchanged.

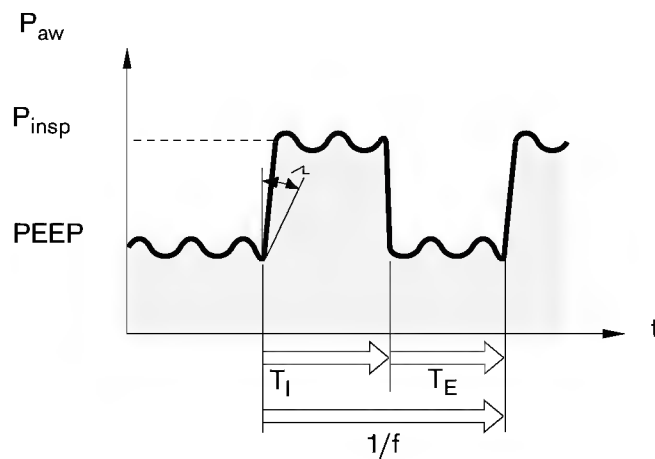


Fig. 49: BIPAP waveform

The rate of pressure increase from the lower pressure level to the upper pressure level is adjusted with the $\triangle$ setting. The effective time for the pressure increase cannot exceed the set inspiratory time T_{insp} . This ensures that the upper pressure level P_{insp} is always attained during inspiration. The change-over from controlled ventilation to weaning and eventually completely spontaneous breathing is achieved by gradually reducing the inspiratory pressure P_{insp} and/or the frequency f until the patient breathes spontaneously.

15.9 APRV (Airway Pressure Release Ventilation)

APRV is a ventilation mode for spontaneous breathing at a continuously positive airway pressure with short-time pressure release. This ventilation mode is suitable for patients with a disturbed gas exchange function. The patient breathes spontaneously at a high pressure level P_{high} for an adjustable period of time T_{high} . In case the expiratory time T_{low} is very short, Evita 4 will switch over to a low pressure level P_{low} . The normal pulmonary areas will be evacuated, the "slow" ones will change their volume insignificantly.

This mode serves to improve the ventilation/perfusion ratio in case of a disturbed gas exchange function.

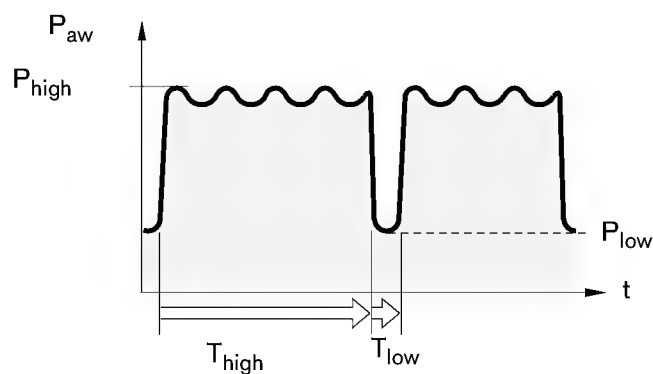


Fig. 50: APRV waveform

15.10 MMV (Mandatory Minute Volume)

In the MMV ventilation mode a mandatory breath will only be applied in case of insufficient spontaneous breathing falling below a preset minimum ventilation (unlike in SIMV). This minimum ventilation is defined by the tidal volume V_T and frequency f settings and is the product of $V_T \times f$.

Unlike SIMV, in MMV mandatory breaths will not be applied at regular intervals but only when insufficient ventilation is likely to occur.

The frequency of the mandatory breaths depends on the extent of spontaneous breathing:

- No mandatory breaths will be applied if the spontaneous breathing activity is sufficient.
- If the spontaneous breathing activity is insufficient, mandatory breaths will be applied in accordance with the set tidal volume V_T . If there is no spontaneous breathing activity at all, the mandatory breaths will be applied at the set frequency f .

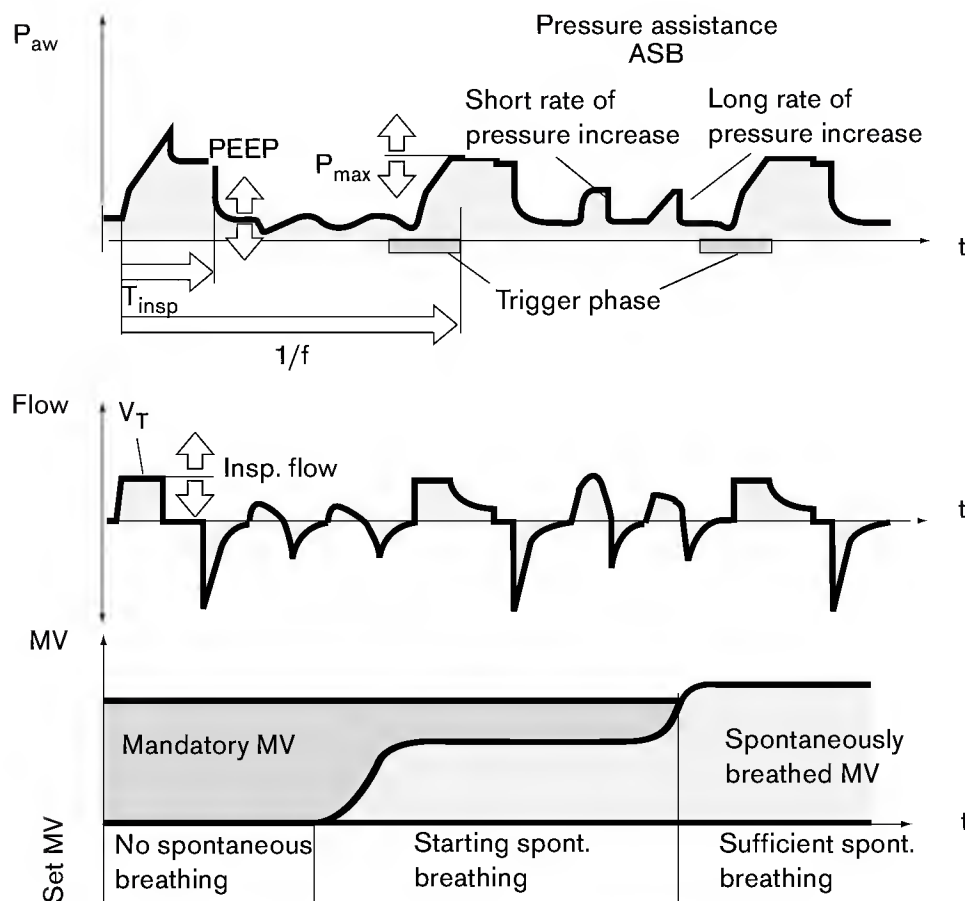


Fig. 51: MMV waveform and diagram

Evita 4 continuously balances the difference between spontaneous breathing and the set minimum ventilation. As soon as the balance is negative due to insufficient spontaneous breathing, Evita 4 will apply a mandatory breath with the set tidal volume V_T and the balance will be positive again.

Experience has shown that patients usually breathe very irregularly. Phases of weak and heavy respiration alternate. In order to account for such individual fluctuations, the balance also includes the portion exceeding the set minimum ventilation. Evita 4 reduces this value within 7.5 seconds max. after apnoea.

Consequently, the response time of Evita 4 between the incidence and application of the mandatory breaths automatically adapts to the previous spontaneous breathing:

If spontaneous breathing was approximately the same as the set minimum ventilation, the machine's response time will be within the IMV time. If, however, the previous spontaneous breathing of the patient was significantly higher than the set minimum ventilation, Evita 4 will tolerate a longer respiratory pause. In extreme situations such as the case of sudden apnoea after a period of intensive spontaneous breathing, the response time will be approx. 7.5 seconds plus the trigger time, however, 1 IMV time minimum.

Response times greater than 15 seconds can only occur if the minimum ventilation was set to a very small value at a very low frequency f .

In this case Evita 4 will give an apnoea alarm which is silenced upon the onset of the mandatory breaths. If the set IMV time is longer than the $T_{\text{apnoe}} \setminus$ alarm limit and if there is no spontaneous breathing between the mandatory breaths, apnoea alarm will be given at regular intervals.

Example:

$f = 3/\text{min} = \text{IMV time} = 20 \text{ seconds}$

$T_{\text{apnoe}} > 15 \text{ seconds}$

This method serves to prevent that during irregular spontaneous breathing a mandatory breath is applied too early while an alarm will be given in case ventilation is insufficient for a longer period of time.

15.11 Measurement Manoeuvres

15.11.1 Occlusion Pressure

The pressure in the mouth measured under short-term occlusion at the start of inspiration is the basis for measuring the respiratory drive since the pressure is not influenced by physiological processes of compensation, e.g. reflex apnoea, increase of drive, within 100 ms. This pressure does not in any way depend on the relevant muscular power of the diaphragm. Therefore, the negative pressure in the mouth $P_{0.1}$ after 0.1 seconds is a direct measure of the neuromuscular respiratory drive.

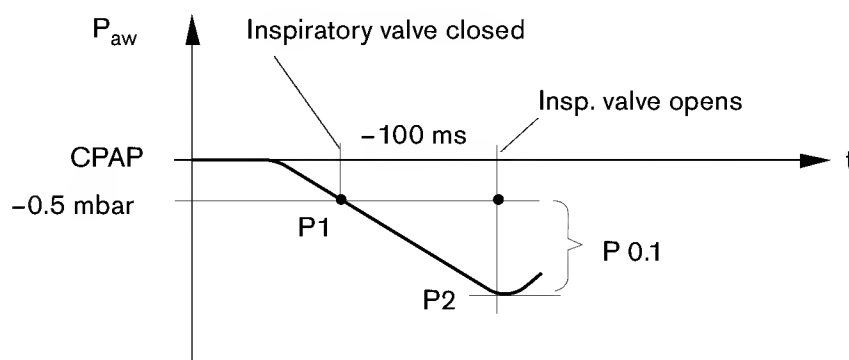


Fig. 52: Occlusion pressure waveform

In patients with healthy lungs the pressure $P_{0.1}$ will be approx. 3 to 4 mbar during regular respiration. A high $P_{0.1}$ value signifies an elevated respiratory drive which can only be sustained for a limited period of time. $P_{0.1}$ values in excess of 6 mbar, e.g. in a COPD patient, are indicative of the expected fatigue („Respiratory Muscle Fatigue”).

Measuring the $P_{0.1}$ pressure in COPD-ventilated patients helps to define the time when weaning should be started.

Evita 4 keeps the inspiratory valve closed after the expiratory phase and measures the airway pressure built up by the inspiratory effort in 100 ms. The 100 ms time interval starts when the inspiratory effort of the patient has produced a negative pressure of -0.5 mbar.

The second pressure value is determined after the 100 ms time interval. At the same time, the inspiratory valve opens and the patient continues to breathe normally.

The difference between the two pressure values $P_2 - P_1$ defines the occlusion pressure $P_{0.1}$.

15.12 Intrinsic PEEP

Evita 4 keeps the inspiratory and expiratory valves closed for a period of measurement period 1 so that neither inspiratory gas can enter nor can gas escape from the ventilation system. In the course of this period pressure compensation will occur between the lungs and the ventilation system. Evita 4 measures the pressure waveform.

The initial pressure value is equivalent to PEEP, the value at the end of the closing period is the intrinsic PEEP.

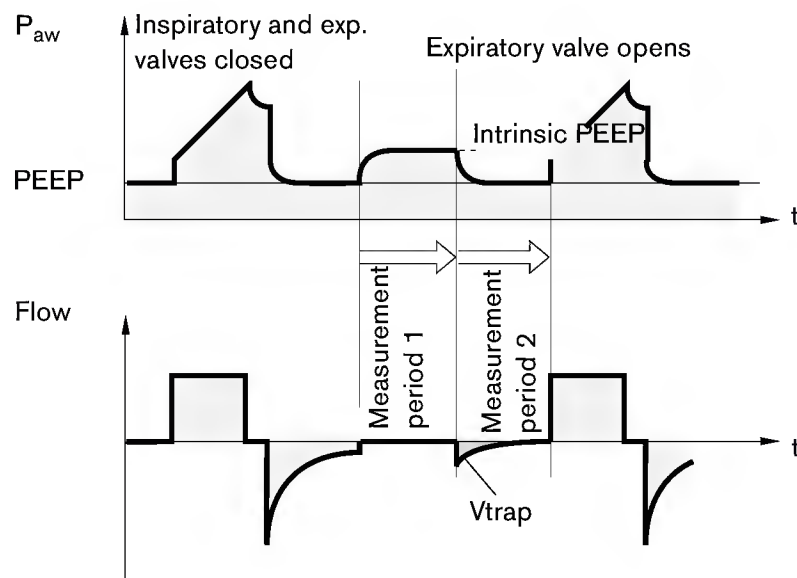


Fig. 53: Intrinsic PEEP waveform

As soon as measurement period 1 is over, Evita 4 opens the expiratory valve and measures the expiratory flow generated by the intrinsic PEEP during a defined measurement period 2. The pressure in the lungs will drop to PEEP level. The measurement will be terminated:

when the expiratory flow has dropped to 0,

at the latest after 7 seconds max. (or 3.5 seconds in paediatric application).

The integrated flow is equivalent to the volume V_{trap} gathered in the lungs on account of the intrinsic PEEP.

Measurement periods 1 for intrinsic PEEP:

- For ventilation of adults: 3 seconds max.
- For ventilation of infants: 1.5 seconds max.

Measurement periods 2 for Vtrap:

- For ventilation of adults: 7 seconds max.
- For ventilation of infants: 3.5 seconds max.

15.13 Inspiratory O₂ Concentration During Medicament Nebulization

CAUTION:

The use of other medicament nebulizers may lead to considerable deviations in the tidal volume and the inspiratory O₂ concentration!

Use medicament nebulizer 84 12 935 (white centre piece) only.

In order to compensate for minor deviations from the set O₂ concentration, the Evita 4 provides mixed gas to drive the medicament nebulizer. This mixed gas is produced when compressed air and oxygen are switched synchronously with inspiration. Consequently, the drive gas of the medicament nebulizer is virtually equivalent to the set FiO₂ concentration.

The diagram shows the possible deviations in the applied O₂ concentration as a function of the set FiO₂ concentration for a minimum inspiratory flow (15 L/min).

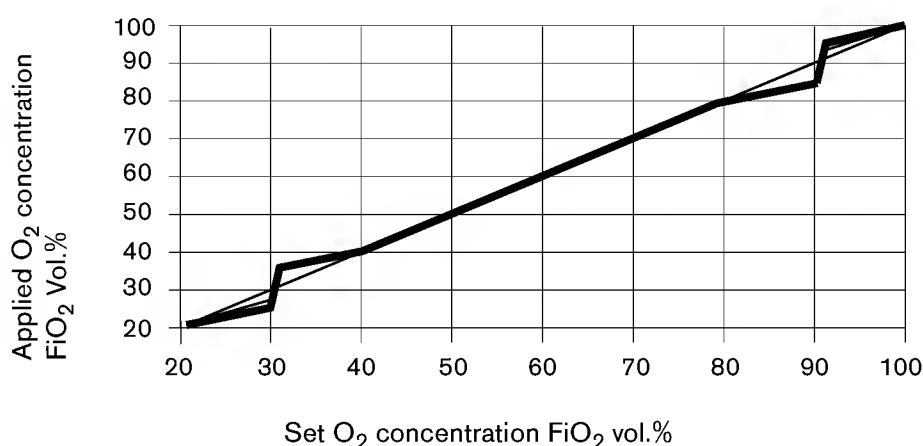


Fig. 54: Diagram of deviations in the applied O₂ concentration

15.13.1 Medicament Nebulizer

After pressing the button the medicament nebulizer is switched on for 10 minutes. At the same time the solenoid valve Y1.4 is switched through in the flow-active inspiratory phase. The medicament nebulizer is supplied with drive gas by the restrictor R1.2. After completion of the inspiratory gas supply phase the solenoid valve Y1.4 is also switched back. The minute volume remains constant while the flow setting is being corrected. After termination of the medicament nebulization the flow sensor S5.1 is automatically glowd clean.

IMPORTANT:

The minimum inspiratory flow is 16 L/min.

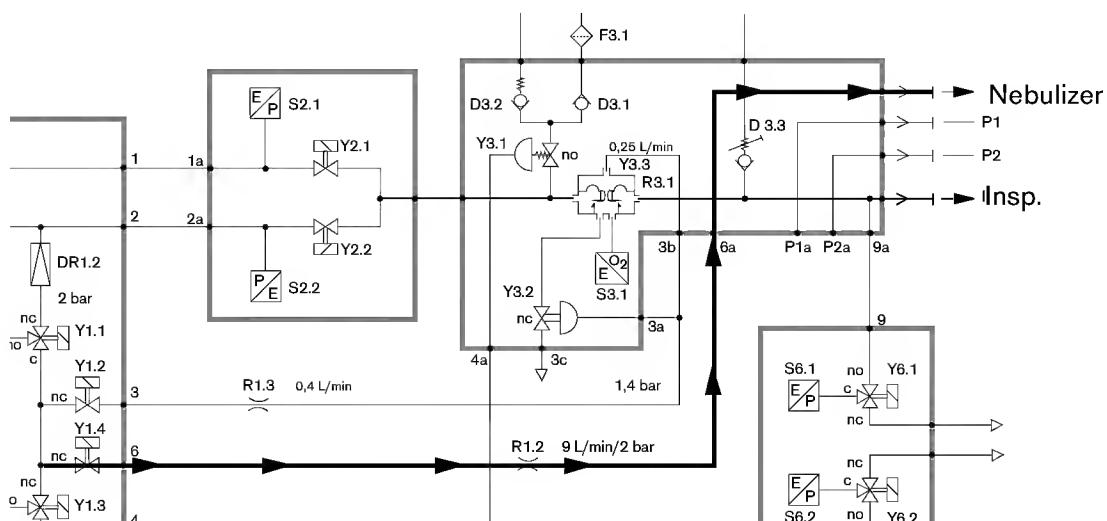


Fig. 55: Nebulizer function diagram

16 Gas mixture

16.1 Operating principle

The air flow and the oxygen flow are metered directly out of the supply lines with one HPSV each. Both sub-flows flow together to the inspiration block in the so-called parallel mixer. Depending on the set FiO_2 (0.21 to 1.00), the total flow to be metered is split into an air sub-flow and an oxygen sub-flow. Sub-flows of less than 5 L/min are no longer metered continuously, but in pulses lasting at least 8 ms and with a constant flow value of 5 L/min. This results in a pulse/pause ratio that corresponds to the sub-flow value.

16.2 Correcting the oxygen HPSV

Corresponding to its operating principle, the HPSV meters a mass flow. Owing to the differing gas density values of the compressed air and the oxygen, different volume flows would therefore be applied if these values were not corrected. Owing to the different gas density values, the portion of the inspiration flow demanded of the oxygen HPSV is therefore boosted by 5%.

16.3 Dependence on the input pressure

With regard to the gas supply, the operating range of the Evita 4 is specified from 2.7 bar to 6 bar gauge pressure. Evita 4 monitors this operating range with the aid of the absolute pressure sensors on the HPSVs on the basis of the following criteria:

- 1) Input pressure always higher than 1.2 relative/absolute
- 2) When the flow obtained is low, input pressure higher than 2.5 bar relative

At low input pressures (below 3 bar gauge pressure), the HPSV can no longer apply high flow demands without errors, i.e. the actually supplied flow is less than the demanded flow. The inspiration flow must be limited for reasons of flow accuracy and thus also for oxygen concentration accuracy reasons.

How this is implemented in the Evita 4:

Prior to the start of an inspiration, the maximum inspiration flow for spontaneous inspiration of the HPSV is defined on the basis of the measured supplied gauge pressure:

$P_{\text{input}} > 4 \text{ bar absolute} \rightarrow \text{max. inspiration flow} = 180 \text{ L/min}$

$P_{\text{input}} < 4 \text{ bar absolute} \rightarrow \text{max. inspiration flow} = 150 \text{ L/min}$

For mandatory inspirations, the inspiration flow is limited by the setting to 120 L/min.

16.4 BTPS/NTPD conversion

The HPSV is a mass source and therefore supplies the flow under NTPD conditions. Nevertheless, the user setting of the inspiration flow or the demand by the demand flow generator is based on BTPS conditions. Prior to control of the HPSVs, the BTPS flow demands must be converted to an NTPD flow supply.

$$\text{Flow\_NTPD} = \text{Flow\_BTPS} \times \frac{P_{\text{umgebung}} + P_{\text{Insp\_End}} - 63 \text{ mbar}}{1013 \text{ mbar}} \times \frac{293\text{K}}{310\text{K}}$$

P_Ambient: value measured by the ambient pressure sensor

P_Insp_Final: measured airway pressure at the end of the last inspiration

17 Function Diagram

Legend

AIR	Compressed air connection	Y3.1	Emergency air valve
O ₂	Compressed oxygen connection	Y3.3	Inspiratory valve
		Y4.1	PEEP/PIP valve
F1.1	Filter	Y5.1	Expiratory valve
F1.2	Filter	Y6.1	3/2-way solenoid valve, insp.
F3.2	Filter	Y6.2	3/2-way solenoid valve, exp.
D1.1	Check valve	S2.1	AIR pressure sensor (HPSV)
D1.2	Check valve	S2.2	O ₂ pressure sensor (HPSV)
D3.1	Check valve	S6.1	Inspiratory pressure sensor
D3.2	Check valve Ý 10 mbar	S6.2	Expiratory pressure sensor
D3.3	Check valve Ý 100 mbar	S3.1	O ₂ sensor
D5.1	Check valve	S5.1	Flow sensor
DR1.1	AIR pressure regulator	R1.1	Flow control 0.08 L/min/2 bar
DR1.2	O ₂ pressure regulator	R1.2	Flow control 9 L/min/2 bar
		R1.3	Flow control 0.4 L/min/2 bar
		R3.1	Flow control (hole in the diaphragm in Y3.3) 0.25 L/min/1.4 bar
		R4.1	Flow control 3.5 L/min/2 bar
Y1.1	3/2-way solenoid valve, O ₂ /AIR		
Y1.2	3/2-way solenoid valve calibration O ₂ -Sensor		
Y1.3	3/2-way solenoid valve, venting		
Y1.4	3/2-way solenoid valve, nebulizer		
Y2.1	HPSV AIR (high-pressure servo-valve) parallel mixer		
Y2.2	HPSV O ₂ (high-pressure servo-valve) parallel mixer		

17.1 Pneumatics function diagram

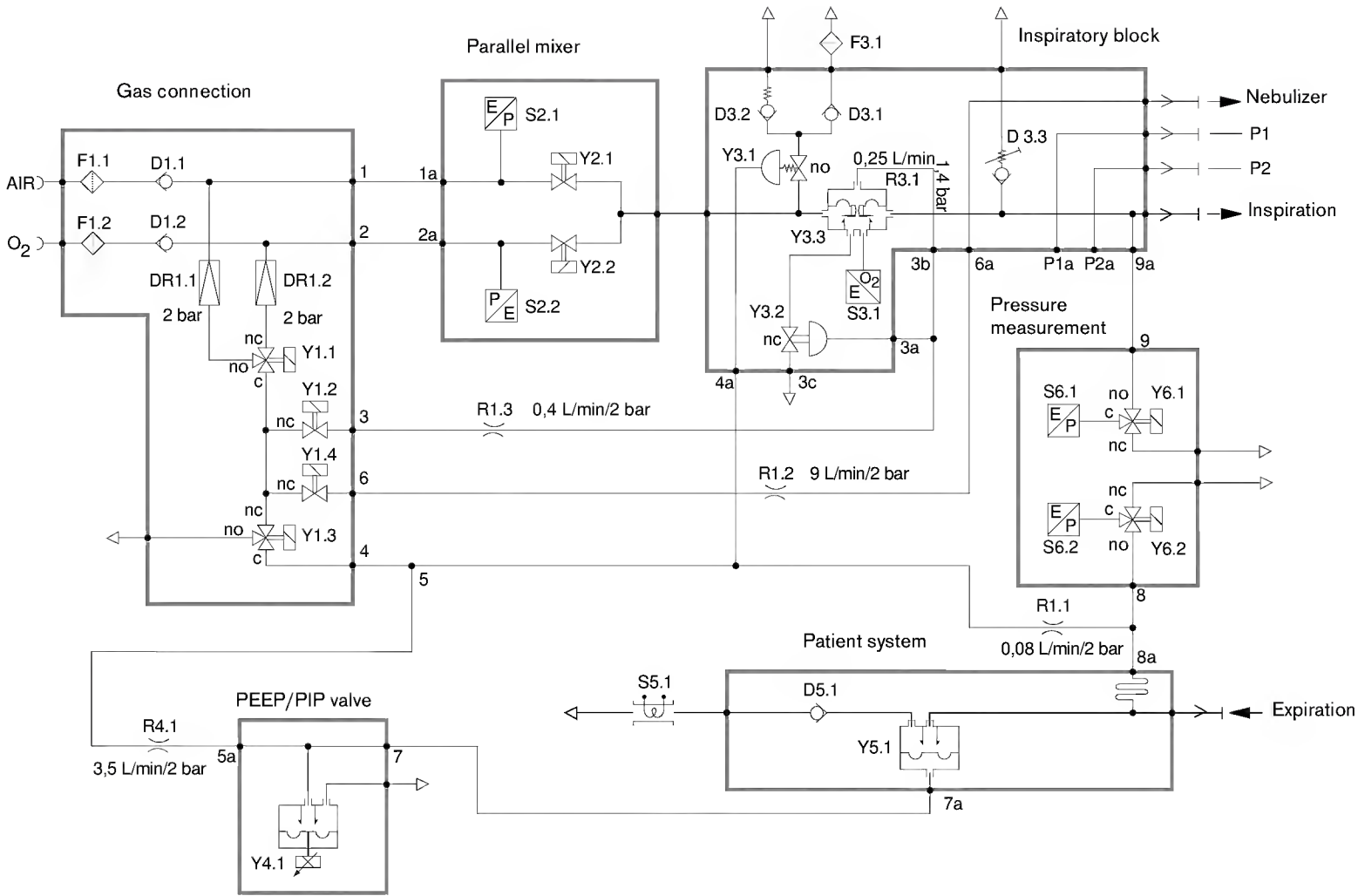


Abb.56: Pneumatics function diagram